UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Sage Chemical, Inc. and TruPharma, LLC, *Plaintiffs*, v. Supernus Pharmaceuticals, Inc., Britannia Pharmaceuticals Limited, and US WorldMeds Partners, LLC, *Defendants*.	Civil Action No. 1:22-cv-1302 **COMPLAINT** **DEMAND FOR JURY TRIAL** **PUBLIC REDACTED VERSION**

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1. Plaintiffs Sage Chemical, Inc. ("Sage") and TruPharma, LLC ("TruPharma") bring this antitrust action for treble damages and injunctive relief as a result of an anticompetitive scheme by Defendants Supernus Pharmaceuticals, Inc. ("Supernus"), Britannia Pharmaceuticals Limited ("Britannia"), and US WorldMeds Partners, LLC ("US WorldMeds") (hereinafter "Defendants"), to restrain generic competition with Defendants' Apokyn® branded injectable apomorphine cartridges, a critical drug needed to treat patients suffering from debilitating symptoms associated with advanced Parkinson's disease.

OVERVIEW OF THE ACTION

2. Defendants have each engaged in anticompetitive and exclusionary acts that contribute to a pervasive course of conduct directed at one unlawful aim—to preserve Apokyn®'s monopoly profits shared among Defendants by delaying and then suppressing competition from the first generic market entrant.

3. Defendants engaged in a series of conspiratorial and exclusionary acts to unlawfully maintain the Apokyn® monopoly over the U.S. injectable apomorphine market by restraining competition from the A-rated generic alternative that was approved by the U.S. Food & Drug Administration ("FDA") earlier this year for use with the same reusable injection pens provided to patients with Apokyn®. Despite a lack of patent protection or regulatory exclusivity for over ten years, Defendants acted together to delay the entry of the first generic version of Apokyn®, to cut Plaintiffs off from the supply of compatible apomorphine injection pens, and to substantially foreclose critical distribution channels for the generic.

4. Defendants' anticompetitive scheme to maintain the Apokyn® monopoly continues to harm competition, patients, payers, and Plaintiffs to this day. As a result of Defendants' unlawful conduct, Apokyn® continues to make up nearly all of the U.S. injectable apomorphine market. As a result, patients and payers, including state and federal Medicaid and Medicare

programs, continue to be forced to pay supracompetitive prices. Supernus, and its predecessor US WorldMeds before it, has exercised and abused its monopoly power by exploiting patients and payers with repeated price hikes raising the price for Apokyn® by more than 30% in just the last five years. Critically, some patients have been forced to forgo these medically necessary treatments because they either cannot afford Apokyn®'s monopoly prices or cannot access the generic, which insurers direct patients to purchase. Thus, in addition to causing Plaintiffs substantial damages, Defendants have harmed those suffering from advanced Parkinson's disease by blocking patient access to the generic alternative to the brand and have unjustifiably cost patients and payers for apomorphine injectable products tens of millions of dollars in overcharges.

5. As detailed below, as part of their anticompetitive scheme, Defendants unlawfully delayed FDA approval of the generic product by: (i) restricting access to samples of the branded drug and injection pen needed for FDA tests; (ii) filing a series of objectively and subjectively baseless sham citizen petitions arguing in bad faith, among other things, that the FDA could not approve any generic unless the applicant had access to its own supply of compatible apomorphine injection pens; and (iii) agreeing behind the scenes to restrict Plaintiffs' access to the very pens Defendants argued were necessary for FDA approval. Unsatisfied with the ill-gotten gains Defendants reaped by delaying the first generic's market entry, following FDA approval, Defendants (i) continue to unlawfully restrict access to the supply of compatible apomorphine injection pens needed to dispense the generic cartridges; (ii) falsely claim that Apokyn® is the only injectable apomorphine therapy approved by the FDA; and (iii) foreclosed critical distribution channels by coercing pharmaceutical customers to cancel orders of Plaintiffs' generic apomorphine cartridges approved by the FDA for use with Apokyn® injection pens. While courts must look to a monopolist's conduct taken as a whole, rather than considering each aspect in

isolation, any one of these exclusionary acts is sufficient to support Plaintiffs' monopolization claim.

Treatment of Parkinson's Disease

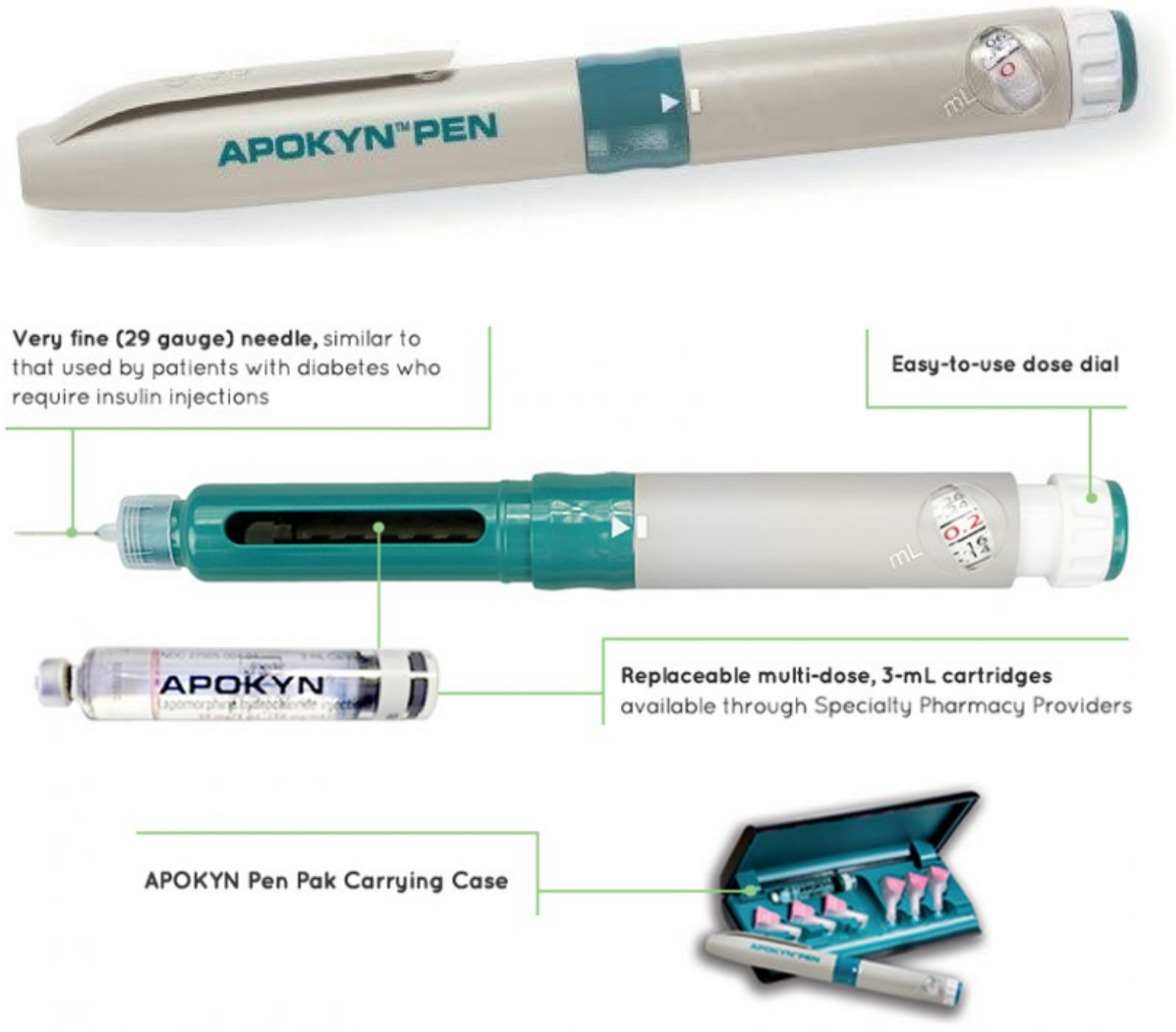
6. Parkinson's disease is a progressive disorder that affects the nervous system and the parts of the body controlled by the nerves, causing tremors, loss of motor function, dementia and death. Parkinson's disease is primarily treated by levodopa, a medication that increases dopamine levels in the brain, but with long-term use the effects of this medication wear off before a new dose can be taken. The amount that levodopa can be increased is limited because increased dosages can cause a condition characterized by uncontrolled and abnormal movements. Once levodopa starts to wear off, patients may begin suffering again from Parkinson's disease symptoms in what are called "off episodes" before the next levodopa dose can be taken. Patients suffering from Parkinson's can experience different symptoms during "off" episodes, including unpredictable, sudden episodes when the patient experiences significant difficulty moving (hypomobility), the return of tremors, feelings of anxiety, stiffness, and/or intense, painful muscle cramping (dystonia).

7. To alleviate acute symptoms and suffering during "off" episodes before the next levodopa treatment can be administered, patients can be injected with apomorphine hydrochloride, which is a dopamine agonist that imitates the effect of dopamine in the brain and can alleviate symptoms in as little as ten minutes.

8. Because "off" episodes can be unexpected and result in debilitating periods of hypomobility that interfere with patients' ability to complete basic daily tasks, the speed "off" episode treatments can reach the brain and alleviate symptoms is important.

9. Defendants' branded drug, Apokyn®, also known as apomorphine hydrochloride injection, is a prescription-only medication that is a non-ergoline dopamine agonist indicated for the acute, intermittent treatment of hypomobility, *"off"* episodes ("end-of-dose wearing-off" and unpredictable "on-off" episodes) in patients with advanced Parkinson's disease. Patients taking subcutaneous apomorphine hydrochloride saw 95% of "off" episodes reversed, with improvement beginning as quickly as 10 minutes post-dosing in clinical studies.

10. Apokyn® is FDA-approved in the form of multi-dose cartridges, 30 mg/3 mL (10 mg/mL) for use with a reusable pen injector (the "Apokyn® pen") for subcutaneous injection, as shown below.



See https://www.apokyn.com/apokyn-pen.

11. The Apokyn® pen is a multi-use pen that is intended to be reused many times. Apokyn® is sold in packs with multiple, replaceable multi-dose apomorphine cartridges. The only qualification Defendants place on the number of times an Apokyn® pen can be reused by the same patient in its instructions for use is that a patient should not "use the pen for more than 1 year after the first use or after the expiration date on the carton."

12. In 2004, Apokyn® was approved by the FDA and granted orphan drug status under the United States Orphan Drug Act. Orphan drugs are granted exclusivity providing seven years without generic competition for the approved orphan designation.

13. In April 2011, the orphan drug exclusivity expired. As of that date, there were no unexpired patents in the FDA Orange Book for this product.

The Monopolistic Scheme

14. In November 2011, French drugmaker Ipsen sold its North American development and marketing rights for Apokyn® to UK-based Britannia Pharmaceuticals, which was then part of Germany's STADA Arzneimittel.

15. By no later than January 15, 2016, Britannia appointed US WorldMeds, LLC (then an entity owned and controlled by Defendant US WorldMeds) as its distributor of Apokyn® for resale in the United States. Defendants Britannia and US WorldMeds knew that if a generic version of Apokyn® was approved by the FDA, the brand product would lose significant revenue.

16. To preserve Apokyn®'s monopoly profits shared among Defendants, Defendants US WorldMeds and Britannia, and starting in 2020, Defendant Supernus, which acquired US

WorldMeds, LLC executed individually and together a multi-part scheme to delay and restrain generic entry.

17. First, Defendants created a limited distribution network and imposed restrictions prohibiting distributors and purchasers from providing Apokyn® to generic companies or their agents. By restricting access to branded Apokyn®, Defendants restrained competition from generic manufacturers that needed Apokyn® samples to develop this molecule for which there was no patent protection. The FDA requires any generic applicant to conduct testing comparing its product to the branded product, and in some instances, to provide samples of both products to the Agency. In a public statement issued on May 17, 2018, then FDA Commissioner Scott Gottlieb, stated that "[an] abuse that I've spoken about often is a practice by brand companies to create obstacles for generic developers in purchasing samples of their brand drugs." As described herein, Apokyn® distribution and resale restrictions made it exceedingly difficult for generic companies to purchase Apokyn® necessary to conduct the FDA-required tests and to respond to FDA requests for samples.

18. Second, US WorldMeds filed not one, but a series of three sham citizen petitions that had the purpose and effect of delaying and obstructing the FDA review process of any application referencing Apokyn® as the reference listed drug (RLD). Defendants recycled and repackaged previously rejected arguments in a serial fashion for the purpose of complicating the FDA review process and delaying final approval, and thereby delaying competition. Each of these sham petitions was denied, but as a serial filer making repetitive arguments, it is plain that Defendants acted to delay approval of a generic product in order to maintain the Apokyn® monopoly.

19. Third, at the same time that US WorldMeds was filing serial petitions arguing that a generic applicant like Plaintiff Sage must supply a compatible apomorphine injection pen in order to obtain FDA approval, Defendants interfered with Sage's relationship with the sole supplier of compatible apomorphine injection pens. Upon information and belief, Defendants learned that an Abbreviated New Drug Application ("ANDA") applicant was in the process of securing a supply of compatible pens from Becton, Dickinson and Company ("BD"). Such a supply agreement would have enabled Plaintiffs to obtain FDA approval more quickly and to launch not only a competitive injectable apomorphine cartridge product, but also a compatible injection pen that could be used for initial prescriptions in addition to refills. By September 2019, Defendants US WorldMeds and Britannia renegotiated its supply agreement for compatible pens from BD in order to restrain this supplier from selling compatible pens to Sage or anyone else who would use such pens in the United States to administer "apomorphine to treat symptoms of Parkinson's disease." Under this unlawful exclusionary agreement, Defendants required BD to "terminate" its on-going negotiations concerning the possibility of supplying Sage compatible reusable pens and to refrain from any such future negotiations with anyone other than Defendants.

20. Defendants' prior course of dealing with BD, including a February 2019 supply agreement that did not restrain competitive sales, demonstrates that the exclusionary provisions inserted in September 2019 were not reasonably necessary to achieve any procompetitive benefit. Prior to the September agreement, BD had already agreed to terms with Defendants to supply pens on a non-exclusive basis, in accordance with BD's policy of not entering into exclusive agreements. [redacted] Tellingly, the subsequent exclusionary agreement only restricted BD's ability to supply these reusable pens

for use to treat the small population of patients taking apomorphine to control their symptoms of Parkinson's disease. BD remained free to supply such pens for the treatment of other conditions, indicating that the exclusionary provisions were not legitimately intended to ensure the supply of pens to Defendants, which could have been accomplished instead with the less restrictive alternative of reserving a specified amount. The September renegotiation of the supply agreement reached just months earlier was thus unquestionably entered into by Defendants for the intended purpose and effect of unlawfully excluding competition and maintaining the Apokyn® monopoly.

21. Fourth, after Plaintiffs' generic cartridge product was approved by the FDA, Defendants undertook a systematic effort to thwart the launch of the generic product and to maintain this monopoly. Defendants also tortiously interfered with Plaintiffs' contracts to sell the generic product.

22. Defendants sell the Apokyn® product to a limited network of three primary specialty pharmacies. In recent years, the two specialty pharmacies, Accredo Health Group, Inc. and Caremark LLC, accounted for more than 35% individually and more than 80% collectively of the total revenue from sales of Apokyn®. Upon learning that the FDA approved Sage's abbreviated new drug application, or ANDA, and that the network pharmacies had contracted with Plaintiffs to purchase generic injectable apomorphine cartridges, Supernus threatened these specialty pharmacies with legal action, termination of contracts, and/or the discontinuation of access to the Apokyn® pen to coerce them to only dispense the Apokyn® cartridge and to refuse to purchase or dispense generic apomorphine cartridges, even for refills.

23. These threats were coercive and effective. The network pharmacies cancelled orders, returned previously purchased generic product, and/or directed their wholesalers to return the generic product wholesalers purchased from Plaintiffs to service the contract between Plaintiffs

and the pharmacies. The network pharmacies have accepted Defendants' conditions and have since ceased the planned purchases of the generic cartridge product.

24. Defendants have taken the anticompetitive position that no patient, pharmacy, or healthcare provider may use Plaintiffs' lower cost, FDA-approved, generic apomorphine cartridge product with the unlawfully restricted Apokyn® pen for which there are no available substitutes—*even if a patient has already acquired an Apokyn® pen, which the FDA has expressly determined to be suitable for use with Plaintiffs' generic apomorphine cartridges*. Moreover, because of Defendants' exclusionary agreement with BD, Plaintiffs were not permitted to supply reusable pens under another name from BD to patients with Parkinson's disease, pharmacies, or health care providers for use with generic apomorphine cartridges.

25. Finally, Supernus has further artificially depressed demand for generic apomorphine cartridges by falsely advertising on its website that Apokyn® "is the only FDA-approved therapy in the United States for the acute intermittent treatment of hypomobility—*off* episodes."

26. The purpose and effect of Defendants' anticompetitive conduct has been to thwart generic competition and to protect Defendants' supracompetitive revenues resulting from Apokyn®'s monopoly position and successive price increases. Defendants' misconduct continues to this day. Absent Defendants' anticompetitive conduct, Apokyn® would have faced generic competition years ago, and generic penetration upon approval would have been significant.

27. Patients who need injectable apomorphine have been denied the opportunity to purchase a lower-cost, generic version, forcing them and payers to expend tens of millions of dollars more per year for this medication—or to forego the medication altogether.

28. Defendants' exclusionary agreements and anticompetitive conduct has allowed them to control access to apomorphine for subcutaneous injections and enabled them to maintain higher prices and exclude generic competition for this treatment.

29. The exclusionary restrictions imposed by Defendants have no procompetitive benefit or medical justification—they merely protect Defendants' profits. Absent Defendants' anticompetitive conduct, Apokyn® would now be losing substantial share to Plaintiffs' generic alternative, which is substantially less expensive than Apokyn®.

30. This is an action for treble damages and permanent injunctive relief against Defendants for violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2; Section 3 of the Clayton Act, 15 U.S.C. § 14; the New Jersey Antitrust Act, N.J.S.A. 56:9-3, 9-4(a), Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a); and common law. In addition to treble damages, among other relief, this action seeks a declaration (i) that Defendants' contractual provisions unreasonably restraining Plaintiffs' access to the reusable, compatible injector pens needed to administer the generic are null, void, and unenforceable; (ii) an injunction prohibiting Supernus or other Defendants from continuing to tortiously interfere with Plaintiffs' contracts, orders, and prospective economic advantage; and (iii) an injunction prohibiting Defendants from blocking patients from gaining access to the generic cartridges they need to administer subcutaneous apomorphine injections.

THE PARTIES

31. At all times relevant to this case, Defendant Britannia has been a holder of product rights related to Apokyn®. From at least 2015-2020, Defendant US WorldMeds (directly and through subsidiaries) controlled the U.S. marketing of Apokyn® through agreements with Britannia and others. In April 2020, Defendant US WorldMeds signed an asset sale agreement with Defendant Supernus, which included the U.S. rights to Apokyn® and a development-stage

apomorphine infusion pump product. The transaction closed on or around June 30, 2020. Supernus has since stepped into the shoes of US WorldMeds on agreements with Britannia and others relating to Apokyn®.

32. Plaintiff Sage sought to challenge the Apokyn® monopoly by filing an ANDA for FDA approval to market a generic version. Sage partnered with Plaintiff TruPharma to market and sell the generic.

33. Plaintiff Sage Chemical, Inc. is a privately held pharmaceutical company dedicated to developing and commercializing niche pharmaceutical products. Sage is the holder of the first FDA-approved generic apomorphine cartridge product for subcutaneous injection, which is A-rated to Defendants' Apokyn® product. Sage is incorporated under New Jersey law and maintains a place of business in Hackensack, New Jersey.

34. Plaintiff TruPharma, LLC is a privately held pharmaceutical company focused on commercializing branded and generic prescription drugs for the U.S. market. TruPharma has a diverse portfolio of products distributed across multiple channels. TruPharma partnered with Sage to launch its generic apomorphine cartridge product upon FDA approval. TruPharma is a limited liability company that is organized under Delaware law. TruPharma's principal place of business is in Tampa, Florida.

35. Defendant Supernus Pharmaceuticals, Inc. is incorporated in Delaware. Supernus is a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system diseases. Supernus's principal executive offices are located in Maryland. Supernus has repeatedly committed overt acts in furtherance of Defendants' anticompetitive scheme, including by coercing multiple customers to cancel their contracts and orders of generic apomorphine cartridges.

36. Defendant US WorldMeds Partners, LLC is a limited liability company that is organized under Delaware law with a registered office at 1209 Orange St, Wilmington, Delaware, and with headquarters in Kentucky. US WorldMeds was the owner and operator of the enterprise (including subsidiaries) which conducted the Apokyn® business until at least the sale of this enterprise to Supernus in 2020.

37. US WorldMeds retains a significant financial interest in the future success and continued monopoly over the injectable apomorphine market. According to the terms of its sale to Supernus, US WorldMeds may receive up to $35 million based on achieving U.S. sales thresholds for Apokyn®. US WorldMeds committed multiple overt acts in furtherance of Defendants' anticompetitive scheme, including by entering into the exclusionary agreement with BD to foreclose generic access to reusable apomorphine injection pens and by filing a series of sham citizen petitions to delay generic entry.

38. Defendant Britannia Pharmaceuticals Limited has a registered office at Park View House, 65, London Road, Newbury, Berkshire RG14 UN. As of January 15, 2016, Britannia was the holder of certain Apokyn® Intellectual Property Rights and appointed US WorldMeds, LLC as its distributor of Apokyn® for resale in the United States. Britannia also is a party to the Distribution, Development, Commercialization and Supply Agreement with Defendants that grants certain intellectual property and product rights in relation to Apokyn®, including the right to use and market Apokyn® in the United States. Britannia has an obligation to supply Supernus with Apokyn® for marketing and sale and receives payments related to those sales. Britannia also supplies injectable apomorphine to the European market on an exclusive basis with Stada Pharmaceuticals, under the brand name Apo-Go.

39. Britannia committed an overt act in furtherance of Defendants' anticompetitive scheme by entering into the Defendants' exclusionary agreement with BD to block competitors, patients, and pharmacies from purchasing compatible, reusable pens for use in the United States with generic apomorphine cartridges to treat Parkinson's disease. In the agreement with BD, Britannia agreed to be governed by Delaware law.

40. Britannia has an on-going monetary interest in the sales of Apokyn®. Pursuant to the January 2016 Amended and Restated Distribution, Development, Commercialization, and Supply Agreement, Supernus is obligated to make royalty payments to Britannia based upon U.S. net sales, adjusted for other product related costs for Apokyn® and any other commercial products jointly developed under the agreement. Based on this formula, Defendant Supernus pays Britannia an effective royalty rate in the mid-thirties percent of U.S. net product sales.

AGENTS AND CO-CONSPIRATORS

41. Various persons who are not named as defendants have participated as co-conspirators in the violations alleged herein and have performed acts and made statements in furtherance thereof. These other entities have facilitated, adhered to, participated in, and/or communicated with others regarding Defendants' unlawful activities. Plaintiffs reserve the right to name some or all of these entities as defendants at a later date.

JURISDICTION AND VENUE

42. This action arises, in part, under Section 16 of the Clayton Act, 15 U.S.C. § 26, to prevent and restrain violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and Section 3 of the Clayton Act, 15 U.S.C. § 14; under Section 4 of the Clayton Act, 15 U.S.C. § 15, to compensate Plaintiffs for their damages; and under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). This Court has jurisdiction over the federal law claims alleged herein pursuant to 15 U.S.C. § 15 and 28 U.S.C. §§ 1331, 1337.

43. This action arises, in part, under the New Jersey Antitrust Act, N.J.S.A. 56:9-3, 9-4(a). This Court has supplemental jurisdiction over Plaintiffs' claims arising under these laws pursuant to 28 U.S.C. § 1367 because the facts alleged herein support antitrust claims under both federal and New Jersey law.

44. This Court has personal jurisdiction over Supernus, US WorldMeds, and Britannia pursuant to Section 12 of the Clayton Act, 15 U.S.C. § 22, because each Defendant may be found or transacts business in Delaware, as demonstrated by either the state of incorporation and/or entering into one of the exclusionary agreements at issue in this action, which provides that the "agreement shall be governed by and construed in accordance with the internal laws of the state of Delaware."

45. This Court also has personal jurisdiction over each Defendant because each Defendant regularly does and solicits substantial business in Delaware, either directly or through intermediaries, is continuously and systematically present in Delaware, and/or has established minimum contacts with Delaware, in particular by registering to do business in the state of Delaware, maintaining a registered agent for service of process in Delaware, doing substantial business with third parties in Delaware, conducting banking with financial institutions in Delaware/and or repeatedly availing itself of use of the courts in this district. There is personal jurisdiction over Defendant Britannia by virtue of its choice: (1) to enter into an exclusionary contract governed by Delaware law; (2) to contract and otherwise conspire with US WorldMeds, a Delaware corporation; (3) to engage in conduct that harmed Plaintiff TruPharma, a corporation organized under the laws of Delaware; and (4) to restrict pharmacies' and patients' access to compatible apomorphine self-injector pens and restrain price competition in Delaware. In light of Defendants' substantial contacts with Delaware, the exercise of jurisdiction over Defendants

would not offend traditional notions of fair play and substantial justice. Further, Defendants' unlawful conduct alleged herein was directed at, and had the intended effect of, causing injury to Plaintiffs, companies with a presence in this district. The effects of the unlawful conduct alleged below were felt by Plaintiffs, as well as by pharmaceutical customers, payers, and patients in this district.

46. Venue is proper in this district pursuant to Section 12 of the Clayton Act, 15 U.S.C. § 22 because the two domestic entity Defendants were incorporated or organized within this district, and the foreign entity contracted and conspired with those Defendants. Venue also is proper in this district under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred within this judicial district, including the restriction of generic sales to pharmacies and patients that continue to be harmed in this district, and Defendants agreed as part of its scheme to be governed by Delaware law in their agreement with BD to exclude Plaintiffs and all others from purchasing reusable pens that are compatible with injectable apomorphine cartridges needed to treat advanced Parkinson's disease symptoms.

STATUTORY AND REGULATORY BACKGROUND

47. Before marketing a new drug in the United States, a manufacturer must obtain FDA approval for its new drug application ("NDA"). Once approved, new drugs generally are called "brand-name" drugs because they are marketed under a trade name or trademark for the drug, rather than the chemical name of the drug's active ingredient.

48. Before marketing a generic drug in the United States, a manufacturer must obtain FDA approval for an ANDA. Generic drugs are uniquely close competitors to their branded counterparts and are a critical part of lowering prescription drug prices in the United States. A generic drug contains the same active ingredient as the brand-name drug, but typically sells at a

lower price than the brand-name drug. Achieving cost savings through generic substitution is critical for expensive specialty treatments like Apokyn®.

49. All 50 states and the District of Columbia have drug substitution laws that encourage and facilitate substitution of lower-cost, A-rated, generic drugs for branded drugs. When a pharmacist fills a prescription written for a branded drug, these laws allow (in some states, require) the pharmacist to dispense an A-rated generic version of the drug instead of the more expensive branded drug, unless a physician directs or the patient requests otherwise. Conversely, these laws generally do not permit a pharmacist to substitute a non-A-rated drug for a branded drug. Nor do they permit a pharmacist to substitute a similar drug with a different mode of delivery, like a sublingual medication as opposed to an injection.

50. Because of these cost savings, many third-party payers of prescription drugs (e.g., health insurance plans, Medicaid and Medicare programs) have adopted policies to encourage the substitution of A-rated generic drugs for their branded counterparts. As a result of these policies and lower prices, many consumers routinely switch from a branded drug to an A-rated generic drug upon its introduction.

51. Congress enacted the Drug Price Competition & Patent Term Restoration Act, which is commonly known as the Hatch-Waxman Act, to increase the availability of low-cost generic drugs by expediting the FDA approval process for generic drugs. Under the Hatch-Waxman Act, manufacturers of brand-name drugs are required to identify the list of patents that correspond to each approved brand-name drug, and that list of patents is published by the FDA in what is commonly known as the "Orange Book." To preserve incentives for manufacturers to invest in the development of new drugs, the Hatch-Waxman Act also provides that brand-name manufacturers may be entitled to exclusivity for new drugs for a prescribed period of time.

52. Under the Hatch-Waxman Act, generic companies do not need to prove their product is safe and effective. That would be costly, duplicative (because the brand-name company has already done that testing), and unethical (because such proof often requires giving some patients placebos, which is unethical when the drug has already been proven effective). Instead, the generic manufacturer must show its product is a bioequivalent, or the same in all relevant respects, to the branded product. For *in vivo* bioequivalence testing, a generic company must test its product against the branded product by dosing in humans. For certain products, like Apokyn®, *in vivo* bioequivalence testing is not required. Nevertheless, the FDA typically requires comparative analytical and other testing of the RLD product and proposed generic product.

53. A generic company cannot provide comparative data if it cannot obtain samples of the branded drug that it designates as the Reference Listed Drug (or "RLD") and with which it plans to compete. For a number of years prior to 2020, branded companies used a variety of tactics to ensure that generic companies could not obtain those samples. In December 2019, Congress passed the Creating and Restoring Equal Access to Equivalent Samples, or CREATES, Act, bipartisan legislation to stop anticompetitive strategies that delay competition in pharmaceutical markets and increase prescription drug costs.

54. By the time the CREATES Act was enacted, there were 55 generic products for which companies could not obtain the needed branded samples, according to the Food and Drug Administration. CREATES establishes a private right of action that allows developers to sue brand companies that refuse to sell them covered product samples needed to support their applications. If the product developer prevails, the court will order the sale of samples, award attorneys' fees, and litigation costs to the product developer and may impose a monetary penalty on the brand

company. Notably, the CREATES Act expressly provides that nothing in it "shall be construed to limit the operation of any provision of the antitrust laws."

55. Recently, Congress and the FDA have also taken a number of steps to promote generic competition among branded products that are no longer protected by patents or exclusivity and for which the FDA has not approved an abbreviated new drug application, or ANDA, as discussed above, referencing that NDA product. The FDA maintains a list of such drugs and updates this list every six months (in June and December) to improve transparency and encourage the development and submission of ANDAs in markets with little competition. Part I of the list identifies those drug products for which the FDA could immediately accept an ANDA without prior discussion. Through December 2021, Apokyn® was on Part I of this list.

56. Congress also passed a law to incentivize generic companies to seek approval for these drugs. The FDA Reauthorization Act of 2017 (FDARA) created a new pathway to incentivize the development of generic drugs where there is inadequate competition. Under this new pathway (new Section 506H of the Federal Food, Drug, and Cosmetic Act) the FDA may, at the request of an applicant, designate a drug with "inadequate generic competition" as a Competitive Generic Therapy (CGT). At the request of an applicant, the FDA may also expedite the development and review of an abbreviated new drug application, or ANDA, for a drug designated as a CGT.

57. In addition, FDARA created a new type of 180-day market exclusivity for the first approved applicant of a drug with a CGT designation for which there were no unexpired patents or exclusivity listed in "the Orange Book" at the time of original submission of the ANDA. This new 180-day exclusivity (CGT exclusivity) is intended to incentivize competition for drugs that are not protected by patents or exclusivity and for which there is inadequate generic competition.

58. As discussed below, the FDA deemed Apokyn® a drug with inadequate generic competition and appropriate for CGT treatment. Upon approval, Sage was granted CGT exclusivity for its generic product.

DEFENDANTS' ANTICOMPETITIVE SCHEME TO DELAY AND RESTRAIN GENERIC COMPETITION

I. The FDA Rejects Defendants' Initial Attempt to Restrain Generic Competition Before Sage Files an ANDA Seeking FDA Approval to Enter the Market

59. The FDA first approved Apokyn® for injection in the United States in 2004. Apokyn® had 5-year NCE exclusivity that expired on April 20, 2009, and 7-year Orphan Drug exclusivity that expired on April 20, 2011. As of this date, there were no patents listed in the FDA Orange Book for Apokyn®. Despite the expiration of these exclusivities and the absence of any patents, no ANDA referencing Apokyn® as the RLD was approved for the next ten years, until Sage's ANDA was approved in February of 2022.

60. Defendants benefited from an extended period of no competition for Apokyn® in large part because they took steps to prevent or delay generic competitors from obtaining FDA approval.

61. Even before Sage sought to enter the market, US WorldMeds filed an initial citizen petition purportedly seeking to persuade the FDA to institute barriers to generic competition that exceeded what had even been required by Defendants in obtaining approval for Apokyn®. As such, the citizen petition was facially antithetical to the regulatory framework discussed above seeking to alleviate burdens placed on generic entrants to expedite review and approval.

62. As Sage had not yet filed its ANDA seeking FDA approval to enter the market, this first petition was directed to any potential generic competitor. In July 2015, three years before Sage filed its ANDA, US WorldMeds submitted a citizen petition requesting that the FDA require that ANDA and § 505(b)(2) applicants seeking approval of an apomorphine injection drug product

referencing Apokyn®: (1) include a device-use training program, and (2) demonstrate that the applicant's device is the same as the one used with the RLD with respect to key device design attributes and performance. The petition was signed by Henry van den Berg, who remains a Senior Vice President of Defendant US WorldMeds to this day, even after the sale of Apokyn® to Defendant Supernus.

63. The submission included twenty-four pages of complicated analysis of data related to Apokyn®. On January 15, 2016, the FDA wrote US WorldMeds to inform the company that it had yet to respond to the petition because it raised complex issues requiring extensive review and analysis by Agency officials.

64. In September 2017, more than two years after US WorldMeds submitted the petition, the FDA denied the petition in full, noting, inter alia:

> We are denying your first requested action with respect to FDA requiring all applicants seeking approval of drug-device combination products containing apomorphine and intended for use in the advanced Parkinson's disease population (apomorphine drug-device combination products) to demonstrate that their products are supported by a human-factor validated, device-use training program with specified attributes as noted in the Petition.
>
> We also note that Apokyn® is approved with prescribing information directing providers to instruct patients and caregivers on how to use the pen correctly and stating that a caregiver or patient may administer Apokyn® if a healthcare provider determines it is appropriate. The Apokyn® Pen Instructions for Use provide that Apokyn® should not be used unless the patient and the patient's caregiver "have been taught the right way and both[...] understand all of the instructions."
>
> We also note, with respect to the part of your request that the drug-delivery device design meet the needs of the advanced Parkinson's disease population, the Petition goes on to specify that FDA should require applicants demonstrate the needs are met through human factor/usability testing. **However, we do not agree that all applicants must demonstrate that the device design meets the needs of the intended population specifically through human factors and usability testing.**
>
> **We are denying your second requested action, that FDA require ANDA applicants seeking approval of apomorphine drug-device combination products intended for use in the advanced Parkinson's disease population to demonstrate through "clinical human factor/usability" studies that their**

> **products have equivalent device-use training requirements and the same key device attributes and error profile as the RLD**. (Emphasis added.)

65. In explaining its denial in detail, the FDA made a number of statements that highlight Defendants' objectively baseless arguments. For example, the FDA noted that US WorldMeds was advocating for a *higher* approval burden for an ANDA than its own Apokyn® product. The FDA observed:

> **FDA did not require the type of training program requested by the Petition as a condition of approval for Apokyn**, which is the only currently approved drug-device combination product containing apomorphine and intended for use in the advanced Parkinson's disease population. Accordingly, **Apokyn's approved labeling does not include any reference to a training program, and FDA is not aware of any information demonstrating that Apokyn® is not safe or not effective as approved**. (Emphasis added.)

The FDA also made findings supporting the conclusion that the petition was subjectively baseless in that US WorldMeds relied on data from studies that did not support its assertions, noting: "[T]he studies cited were not designed to identify a statistically significant difference in error rates between trained and untrained users, and the Petition does not explain the types of errors observed in the studies. … Additionally, there is no information in the Petition to support extrapolating the results from the studied devices . . . ."

66. The FDA also explained its denial of US WorldMeds' separate request that an ANDA applicant demonstrate the same key device attributes and error profile as the device used with the RLD cartridge. The FDA stated that it had already issued standards for review of such products, and would evaluate products as a part of the normal review process:

> FDA may accept such design differences if they are adequately analyzed, scientifically justified, and do not preclude approval in an ANDA. FDA has proposed in draft guidance that in certain instances, applicants may be able to submit data from comparative use human factor studies to address whether a critical design difference introduces a risk that impacts the clinical effect or safety profile when the proposed generic combination product is substituted for the RLD. The ultimate acceptability of any such design differences would be considered during the course of ANDA review.

67. Therefore, by no later than September 2017, Defendants knew that the FDA rejected the notion that it should adopt special standards with regard to an ANDA referencing Apokyn® as the RLD. This knowledge, however, did not stop Defendants from filing two more objectively baseless citizen petitions asking the FDA in bad faith to create such special standards when assessing Sage's ANDA referencing Apokyn® as the RLD. Defendants did so in bad faith to complicate the FDA's review process, delay generic competition, and to interfere with Sage's ability to compete.

II. Defendants' Actions to Delay FDA Approval of Sage's ANDA and the Entry of Generic Competition

68. Plaintiff Sage filed its ANDA seeking FDA approval of a generic apomorphine cartridge on July 24, 2018. Plaintiff sought approval of a generic apomorphine cartridge that was bioequivalent to the Apokyn® cartridge and compatible for use with the Apokyn® brand multi-use pen.

69. On August 30, 2018, the FDA confirmed that Sage's ANDA was substantially complete and qualified for priority review under the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), 21 U.S.C. 355(q). The FDA also granted Sage's ANDA CGT status due to inadequate competition for the Apokyn® brand product. The FDA provided an initial goal date for completing the review of the original ANDA by March 23, 2019, pursuant to the Generic Drug User Fee Amendments ("GDUFA"), which were enacted to bring greater predictability and timeliness to the review of generic drug applications in order to increase patients' access to safe, high-quality, and affordable generic medicines. The FDA did not ultimately approve Sage's ANDA until February 23, 2022.

70. As detailed below, Defendants' actions during the pendency of Sage's ANDA adversely impacted the FDA review process and delayed FDA approval of Sage's ANDA.

Defendants restricted access to samples of the Apokyn® RLD necessary to respond to the FDA's information requests. Defendants filed a series of sham citizen petitions to delay the FDA review process for Sage's ANDA. And Defendants executed an exclusionary agreement to prevent Sage from obtaining reusable injection pens for use with a generic apomorphine product. All of these actions harmed not only Plaintiffs, but patients suffering from Parkinson's disease who were unable to afford the branded Apokyn® apomorphine product.

A. Defendants Restricted Access to RLD Cartridges and Pens Needed for FDA Testing By Entering Into Exclusionary Distribution Agreements with Specialty Pharmacies

71. Defendants created a restricted distribution system for Apokyn® through a series of exclusionary agreements that unreasonably restrain resales of, and access to, the RLD cartridges and pens that Sage needed to conduct development work on a generic alternative or to otherwise purchase pens for use with the generic. Unfortunately, Sage filed its ANDA before Congress enacted the CREATES Act to address such tactics. As discussed below, Sage had difficulty obtaining samples of the RLD product to respond to FDA requests. This difficulty delayed the review and approval of Sage's ANDA.

72. Despite its efforts, Sage had been unable to obtain samples of the RLD prior to filing its ANDA. Because the product did not require *in vivo* bioequivalence testing, Sage filed its ANDA with data on its proposed product and sought instead to persuade the FDA that Sage should not be required to provide data on the RLD product because RLD samples were not available to Sage and the FDA had access to data for the RLD in the NDA.

73. The FDA, however, asked Sage questions that required access to RLD samples in order to provide responsive test data. Defendants' restrictions on access to the RLD Apokyn® cartridge product accordingly became an issue for Sage that delayed the FDA review process.

74. On October 4, 2018, the FDA issued a disciplinary review letter and requested "at least 5 samples of the proposed product for each strength, and at least 3 samples of each strength of the RLD" (i.e., the reference listed drug, Apokyn®) in order to complete a clinical review. The FDA stated: "If you do not submit the requested information (samples) by October 18, 2018 the listed information requests may be incorporated in a complete response letter."

75. Normally, an ANDA applicant such as Sage would easily obtain sufficient samples of the branded drug by purchasing them through normal distribution channels, such as drug wholesalers. Defendants, however, had apparently entered into agreements with wholesalers and distributors preventing the sale of the Apokyn® product to licensed pharmacies unless the pharmacy was on an approved buyer list and had agreed to restrict distribution of the product. Defendants sought to prevent sales to generic companies like Sage.

76. By email dated October 5, 2018, Sage informed the FDA as follows: "The RLD is not available. Sage has been unable to procure this and therefore cannot supply FDA with the requested samples. What does the Agency suggest?" On October 10, 2018, the FDA responded: "In that case, please provide dimensions of the RLD and proposed generic glass cartridges and provide pictures of the RLD and proposed generic cartridges. Explain why there is no difference in dimensions and functionality between the RLD and the proposed generic." Sage provided the requested information to the FDA.

77. On January 11, 2019, the FDA issued another disciplinary review letter, and among other requests, stated: "Please provide RLD test results and provide side-by-side comparison with ANDA drug product results." The FDA closed its letter with the statement: "If you do not submit a complete written response by 2-11-19, these initial deficiencies may be incorporated in a complete response letter."

78. Following this disciplinary review letter, Sage again reached out to sources seeking RLD samples and was told it was unavailable. One source stated that wholesaler's site would not allow it to order the product and returned a message: "Due to manufacturer limitations on distribution, this product is only available through a limited distribution network of specialty pharmacies." Specialty pharmacies, however, would only supply the RLD product directly to patients.

79. On February 11, 2019, Sage responded to the FDA. In response to the question requesting RLD test results, Sage explained:

> The RLD, APOKYN, is unavailable for [procurement] as it is only supplied directly to patients through specialty pharmacies, direct from the manufacturer. Several wholesalers have been contacted in order to obtain RLD. They have indicated that it is only available directly to patients. The manufacturer has limitations on distribution, the product is only available through a limited distribution network of specialty pharmacies. Please refer to the diagram on the following page detailing the steps required to obtain a prescription of RLD APOKYN. . . . Therefore, given the unavailability of the RLD, and that specifications are justified, RLD data would not be needed to further justify our specifications for the product.

80. Sage was hopeful that its explanations would satisfy the FDA and that a timely FDA approval would be forthcoming, but it was not. The FDA issued a complete response letter for the Sage ANDA on June 3, 2019. The complete response letter reiterated the request to provide data with RLD cartridges and comparable data related to compatibility of the generic cartridge with the Apokyn® reusable pen:

> We are unable to evaluate your proposed generic cartridge sample without compatibility data of the proposed generic cartridge's use with the APOKYN® pen. The proposed generic cartridge sample alone is insufficient to support that your proposed generic cartridge can be substituted for the reference product without intervention of a health care professional. Therefore, please submit actual samples of the APOKYN® pen and your to-be marketed cartridge(s) for the comparative analysis.

81. The FDA considered the need to evaluate compatibility with the Apokyn® pen to be a "major" issue, which translated into a longer review cycle and extended goal date for FDA

action. Defendants' strategy of restricting access to RLD samples to delay FDA approval of a generic product was working.

82. Sage continued to contact additional sources, and ultimately received one proposal to supply RLD cartridges at a price of $30,000 per 5-pack—more than five times the list price for Apokyn®. This source also had a months-long lead time. After Sage was unable to find a better source, in July 2019, it placed an order for five packs of RLD cartridges as well as some Apokyn® pens at an approximate price of $150,000. Although Sage was ultimately able to find one source willing to sell samples, albeit at an exorbitant price, Defendants had already succeeded in delaying Sage's ANDA approval.

B. US WorldMeds Files Its Second of Three Sham Citizen Petitions Arguing That the FDA Should Not Approve ANDAs Because Generic Competitors Lack Access to the Injector Pens That Defendants Restricted

83. Knowing that Defendants had severely restricted access to the compatible injection pens needed to complete FDA testing of generic apomorphine cartridges, Defendant US WorldMeds filed another citizen petition on July 1, 2019, arguing that a generic could not be approved without compatible pens and that the pens would not be available for use with generics as a result of Defendants' restrictive agreements.

84. Despite the FDA's September 2017 rejection of its prior citizen petition, Defendants' July 1, 2019 Petition again made objectively baseless requests that the FDA ignore its prior procedures and instead adopt special standards to require "that any ANDA referencing Apokyn® seek approval of both the drug and device constituent parts of Apokyn" and to establish "guidance" purportedly to clarify the circumstances under which the drug constituent part can be approved in an ANDA that does not also seek approval of the device constituent part. The fact that US WorldMeds had already received a response from the FDA rejecting its previous attempt to create special rules for ANDAs referencing Apokyn® demonstrates that this petition was not

only objectively, but also subjectively, baseless and filed in bad faith. Rather than pursuing a legitimate basis for a citizen petition, Defendants were subjectively motivated by a desire to complicate and delay the FDA's review process and generic competition, rather than to achieve actual administrative relief.

85. Indeed, as discussed below, US WorldMeds submitted this citizen petition at about the same time it was negotiating to cut Sage off from the supply of the injector pens it argued were necessary for FDA approval. The close coordination of these exclusionary activities provides compelling evidence that both the citizen petition and the exclusionary agreement with BD were undertaken by Defendants with the anticompetitive purpose and effect of interfering with and delaying Sage's market entry with a generic to unlawfully maintain the Apokyn® monopoly.

86. In its petition, US WorldMeds further admitted that there is no alternative injector pen approved for use with apomorphine hydrochloride to treat advanced Parkinson's patients and exploited the very same exclusionary restrictions that Defendants themselves put in place to threaten that patients would be denied access to Apokyn® pens for use with a generic:

> Currently, APOKYN® is the only approved drug-device combination product containing apomorphine hydrochloride and intended for use in advanced PD patients. **There is no other device constituent part, branded or generic, approved for this use with an apomorphine hydrochloride drug constituent part. Nor, as noted, is there any alternative auto-injector or injector pen separately approved or cleared by FDA with technical specifications and/or intended uses compatible with this use.** Accordingly, in the absence of a device constituent part proposed in an ANDA, a generic drug constituent part would need to rely upon use with the APOKYN® Pen.
>
> **But it cannot be presumed that patients would have access to the RLD's device constituent part (*i.e.*, the APOKYN® Pen) for use with a generic version of only the drug constituent part of the APOKYN® drug-device combination product. Patients who were not previously prescribed APOKYN® will not have access to the APOKYN® Pen because the APOKYN® Pen is dispensed by specialty pharmacies only in connection with an APOKYN® prescription**. For patients who have an APOKYN® Pen because they were first prescribed APOKYN® and then switched to a generic, there is a risk that the APOKYN® Pen will break or malfunction, be lost, or need to be replaced for some other reason

> (*e.g.*, general wear-and-tear). If this occurs, such patients will not be able to obtain a replacement APOKYN® Pen if they no longer are prescribed APOKYN. Additionally, if APOKYN® is discontinued at some point, the APOKYN® Pen no longer would be available even through a prescription for APOKYN. (Emphasis added.)

87. Aside from constituting another anticompetitive act to further delay approval of the generic, these statements are tantamount to an admission that the agreements Defendants have entered into with BD and pharmacies to restrict sales of compatible pens were intended to, and have the effect of, restraining competition from generic apomorphine cartridges that could otherwise be used to refill the compatible injector pen.

C. Defendants Cut Off Sage's Access to the Supply of Compatible Injection Pens That Could Have Obviated the FDA's Need to Respond to US WorldMeds' Sham Citizens Petitions

88. Defendants next sought to block all remaining upstream access to the manufacturer of the only pens "cleared by the FDA with technical specifications and/or intended uses compatible with this use," as described by US WorldMeds.

89. As acknowledged by US WorldMeds in its second citizen petition, Defendants' supplier, BD, is the only manufacturer that makes pens cleared by the FDA with the appropriate technical specifications and that are operated in a manner consistent with the instructions appearing on the Apokyn® labeling. As an ANDA, Sage did not have the option of modifying its label to use its generic cartridge with a different pen.

90. In late 2018 and early 2019, Sage had been engaged in discussions with BD about supplying the same model of reusable injector pen that it supplied to Defendants for use with Apokyn® cartridges. [redacted]

91. US WorldMeds' statements in its citizen petition increased Sage's urgency to move forward with BD and secure its own supply of pens. Access to the same reusable, compatible pens

would not only satisfy the FDA's requests, but would guard against the very issue that Defendants threatened—a discontinuation of the Apokyn® product and the eventual unavailability of pens for any product. If Sage had its own supply of these pens, this also would have rendered Defendants' citizen petition arguments moot and would have removed an additional source of delay.

92. [redacted]

1. Britannia and US WorldMeds Enter a Facially Anticompetitive and Exclusionary Agreement in 2019 to Restrict the Supply of Pens

93. Based on documents disclosed in 2020 following the US WorldMeds/Supernus transaction, the reason for BD's reversal has since become clear. Although Defendants Britannia and US WorldMeds had already entered into agreements with BD, most recently in February 2019, to supply the reusable injection pens used with Apokyn® on a non-exclusive basis, Defendants renegotiated that agreement in 2019 to prohibit any competitive sales of pens used "for the administration of apomorphine to treat symptoms of Parkinson's disease." Under the terms of the agreement executed in September 2019, Defendants compelled BD to immediately "terminate any and all existing discussions or negotiations" concerning these reusable apomorphine injection pens with anyone other than Britannia and US WorldMeds.

94. The September agreement referred back to the supply agreement executed on February 25, 2019, but revised the agreement just to add exclusionary terms restricting competitors' access to BD pens and additional, exclusionary payments to BD.

95. Specifically, the public, redacted version of the agreement provides:

> In regard to the supply of [**] pens **for the administration of apomorphine to treat symptoms of Parkinson's disease** (hereinafter, "**RLPs**"), the Parties, intending to be legally bound, hereby agree as follows:

> [**] shall not, and shall not authorize or permit any of its affiliates, representatives, or agents to, directly or indirectly, (i) **enter into or participate in any discussions or negotiations with any person or group of persons other than USWM, BPL or either of their respective affiliates regarding a Restricted Transaction**, (ii) furnish any non-public information relating to USWM, BPL or either of their respective affiliates or businesses, in all cases for the purpose or with the effect of assisting with or facilitating a Restricted Transaction, or (iii) **enter into a Restricted Transaction or any agreement, arrangement or understanding, including without limitation, any legally binding agreement, letter of intent, term sheet or similar document relating to a Restricted Transaction**. **Immediately upon execution of this letter agreement, [**] shall, and shall cause its affiliates, representatives, and agents to, terminate any and all existing discussions or negotiations with any person or group of persons other than USWM, BPL or either of their respective affiliates regarding a Restricted Transaction**.

Ex. A (attaching agreement) (emphasis added).

96. The sole and specific focus of the agreement's restriction on pens used to administer apomorphine to treat Parkinson's patients demonstrates that Defendants' intended purpose and effect of this provision is to exclude competition and cut off generic competitors from the only source of pens that were compatible with the apomorphine cartridges and approved by the FDA for use with apomorphine cartridges to treat Parkinson's disease.

97. This facially anticompetitive restriction is not reasonably necessary or tailored to achieve any legitimately procompetitive benefit associated with the supply arrangement, as demonstrated by the fact that the exclusionary provision was added after a supply arrangement had already been agreed to between the parties and which did not restrict competitive sales. *Compare* Ex. A (attaching September agreement), *with* Ex. B (attaching February agreement).

98. For example, this restriction cannot legitimately be needed to ensure a steady supply of pens to Defendants because under the terms of the agreement BD could sell an unlimited quantity of pens to other purchasers so long as they are not used to treat Parkinson's disease. Moreover, the number of pens needed to service patients suffering from advanced Parkinson's disease that use either branded or generic apomorphine is very small, and therefore no capacity

constraint can justify this restriction. As Defendants' own instructions note, just one of these apomorphine injection pens is suitable for reuse to administer all of a patients' apomorphine doses for a full year.

99. In any event, Defendants' February agreement with BD already contained a provision regarding the quantity to be delivered to Defendants, which would achieve the same purportedly procompetitive benefit in a less restrictive manner that Defendants themselves agreed was suitable—that is, at least before the threat of generic competition became more pressing. Thus, any effort to defend the exclusionary restrictions added to the September agreement on the basis of ensuring supply would be pretextual.

100. Rather than being justifiable by any procompetitive benefits, the terms of the September agreement and comparison to the February agreement demonstrate that the September exclusivity provisions are facially anticompetitive provisions that were added for the purpose and effect of restraining competitors' market entry, unreasonably restraining competition, excluding competitors, limiting output of pens and generic cartridges that need to be administered with the pens, and raising competitors' costs as well as the costs of patients suffering from advanced Parkinson's disease and payers that share in the costs of apomorphine.

101. While many of the terms of Defendants' exclusionary pen supply agreement are redacted from the public version, it is clear from what is public and the surrounding facts that the agreement is also unreasonably restrictive in breadth and duration.

102. Indeed, under the agreement, Defendants prohibit BD from even participating in any discussions or negotiations about sales of comparable, reusable apomorphine injection pens with anyone besides Defendants while the agreement is in place, which means that Plaintiffs could not even compete for a *future* contract by providing more favorable terms leading up to the renewal

or extension of the agreement. This type of restriction would penalize BD if it were ever able to terminate the agreement, even for cause, because it would lead to a gap in any sales before negotiating with another purchaser, thereby coercing BD not to seek to terminate the agreement no matter how anticompetitive.

103. The anticompetitive terms of Defendants' exclusionary agreement would explain why BD has repeatedly refused to discuss supplying reusable apomorphine pens with Sage since it broke off negotiations in 2019.

104. The public terms of the agreement suggest that BD also cannot simply terminate the agreement. To the contrary, under the terms of the agreement, Defendants can decide on their own to enter into successive "Extended Exclusivity Periods" that extend the exclusionary restrictions by simply providing written notice of their intent to extend the exclusivity and paying a fee.

105. Such payments made specifically for exclusivity are anticompetitive. While the price terms are redacted, BD's capitulation to Defendants' exclusionary demands—particularly in the context of its stated standard policy of never entering into exclusive agreements—suggests Defendants' payments exceed the fair market value for a supply of such pens.

2. US WorldMeds Uses Exclusionary Agreements to Further Delay FDA Approval of Generic Cartridges

106. The citizen petition filed in July 2019 by US WorldMeds just two months before Defendants executed the September 2019 agreement further demonstrates that this agreement was reached for the specifically anticompetitive purpose of cutting off generic competitors' access to the supply of the reusable apomorphine injector pens US WorldMeds argued ANDA filers needed for FDA approval. [redacted] This timing suggests that the exclusionary pen agreement

was reached in principle around the same time US WorldMeds filed its second citizen petition and that the agreement and the petition are related as part of a broader, coordinated strategy to restrain generic entry.

107. At the same time US WorldMeds was complicating the FDA review process with its citizen petition by arguing generics needed to provide their own compatible pens, Defendants were coordinating behind the scenes to block Sage's access to the supply of the very same compatible pens US WorldMeds claimed Sage needed to supply for use with a generic cartridge. Had Sage been able to complete its deal with BD and secure a supply of these compatible pens, it would have rendered moot Defendants' arguments to the FDA. It would have obviated the need for the FDA to consider whether to approve a generic cartridge without direct access to a supply of such pens.

108. Defendants' exclusionary pen agreement thus enabled Defendants to complicate and prolong the FDA's review of Sage's ANDA as a result of US WorldMeds' second sham petition. This same agreement provided another means of later restricting distribution of its branded cartridge by conditioning access to these pens on the agreement not to purchase the generic once it ultimately was approved by the FDA.

109. On November 4, 2019, Sage responded to the FDA's June 3, 2019 complete response letter. By this time and at a cost of $150,000, Sage had secured samples of RLD cartridges and the Apokyn® pen and had been able to submit the comparative data the FDA requested. But it took Sage five months to respond to this complete response letter as a direct result of Defendants' restrictions on the RLD. The procurement alone took four months. Even after it finally procured RLD, Sage still needed to conduct testing and compile the data for submission to the FDA.

110. This latest delay resulting from Defendants' RLD restrictions added to delays caused earlier in the review cycle. If the RLD had been readily available before filing, there would have been no delay in supplying any requested data. If the RLD had been readily available in October 2018 or January 2019, Sage could have quickly obtained it and provided the FDA with the data it requested and within the requested timeframe.

D. The FDA Denies US WorldMeds' Second and Third Sham Citizen Petitions Arguing that ANDAs Should Be Denied Because Generic Competitors Lack Access to the Injector Pens Defendants Restrict

111. On November 27, 2019, the FDA denied US WorldMeds' second citizen petition.

112. The FDA stated: "[W]e deny without comment on the specific requests in your Petition regarding any specific ANDA referencing Apokyn® as its RLD." As the FDA explained:

> There is no evidence that in enacting section 505(q) of the FD&C Act, Congress intended to bypass the application review process or to lessen an ANDA applicant's procedural rights by requiring that the Agency make decisions that constitute final Agency action regarding the approvability of certain aspects of pending applications on a piecemeal basis outside of the process established under the FD&C Act and FDA regulations. Therefore, we do not interpret section 505(q) of the FD&C Act to require that FDA render a final Agency decision within the statutory deadline on the approvability of a specific aspect of an ANDA when a final decision on the approvability of any such ANDA has not yet been made. Accordingly, **we are denying without comment your request that FDA require that any ANDA referencing Apokyn® seek approval of both the drug and device constituent parts of Apokyn**.

113. As to the request that the FDA establish a policy framework that would apply to ANDAs more broadly, the FDA stated:

> The development of a policy framework clarifying such circumstances, if any, raises complex scientific and policy issues that FDA cannot resolve within the 150-day time frame set forth in section 505(q) of the FD&C Act. Therefore, we deny the request to develop such a policy framework at this time, without comment.

114. Like the 2017 denial of US WorldMeds' 2015 citizen petition, the FDA again made clear that it would not address ANDA-specific matters outside the normal FDA review process for such applications.

115. Despite the FDA's November 27, 2019 and 2017 denial before that, Defendants would not relent. US WorldMeds continued to press its baseless claims in bad faith because its serial petitioning served the goal of complicating and delaying approval of a generic. On December 23, 2019, US WorldMeds filed its third citizen's petition based on the same arguments it made previously, and which the FDA denied less than a month earlier. In part, Defendants styled the third petition as an "appeal" of FDA's earlier denials—an objectively baseless argument because no such process exists under FDA regulations. US WorldMeds also added arguments directly targeting Sage's ANDA, ostensibly as a "response" to the comment Sage added to the public docket as a part of the prior petition. Among other bad faith statements, Defendants addressed Sage's statement that the Apokyn® pen should be available to patients regardless of which approved cartridge they choose to use with it:

> [T]he claim that US WorldMeds can "make the pen available to" patients taking the generic product reflects an apparent lack of understanding of the commercial challenges associated with developing a low-volume device like the APOKYN® Pen and securing a reliable supply. . . .
>
> The suggestion that we can "facilitate[]" coordination between the ANDA applicant and device manufacturer to ensure continued compatibility likewise overlooks the practical challenges that would result, given the absence of any commercial relationship between the ANDA applicant and the device manufacturer.

116. While emphasizing the absence of a commercial relationship between Sage and BD, and claiming to be on the side of the small "population of patients" who take this product, Defendants failed to disclose to the FDA that they had three months earlier executed an exclusionary agreement that cut off Sage's negotiations and prohibited the supply of these reusable pens to Sage or to patients with Parkinson's disease who wanted to use a pen with generic apomorphine cartridges. The lack of a commercial relationship that US WorldMeds pointed to as a basis for denying Sage's ANDA was of Defendants' own making and could have been altered by simply not extending the exclusivity it imposed on BD.

117. Sage hardly lacked an understanding of the commercial challenges of sourcing a low volume pen—[redacted] Defendants' subsequent exclusionary agreement cut off that opportunity and Sage's prospective supply of the very type of pen that Defendants argued the FDA should require it to provide.

118. On January 31, 2020, the FDA issued an information request ("IR") relating to the Clinical review, which included the following request: "Please submit actual samples of the RLD cartridge for the comparative analysis." The FDA stated: "If you do not submit a complete response by February 14, 2020, the review will be closed and the listed IRs may be incorporated in a COMPLETE RESPONSE correspondence."

119. Having earlier ultimately obtained the samples at great expense in order to generate comparative data, Sage was able at his point to provide the FDA the samples it requested. On February 14, 2020, Sage submitted its response and told the FDA that two samples were shipped to it via UPS.

120. On March 17, 2020, the FDA issued an information request relating to the Quality section. The FDA asked for a written explanation of how patients would access the Apokyn® pen, and how it would remain compatible with the Apokyn® pen post-approval. The FDA requested a response by no later than March 23, 2020. The FDA also stated: "It has been determined that the quality assessment for this ANDA requires an additional technical consultation. Please note that the quality assessment of the ANDA cannot be fully completed until this technical consultation has been finalized. Therefore, additional requests for information and/or deficiencies may be issued based on the outcome of this technical consultation." But for Defendants' Citizen Petitions and the exclusionary agreement restricting access to compatible pens, no technical consultation

would have been required. If Sage had access to its own compatible pen, the arguments in the Citizen Petition and the need for a technical consultation would have been rendered moot.

121. On March 23, 2020, Sage provided a response to the FDA's questions in the information request. On May 1, 2020, the FDA issued a complete response letter to Sage's November 4, 2019 submission. The complete response letter stated that the FDA determined that it could not approve the ANDA in its present form, but after Sage corrected some minor items, the FDA set a goal date of August 25, 2020 for ANDA approval. Based on the minor requests in the complete response letter, Plaintiffs expected approval on or before the August 25, 2020 goal date.

122. On May 21, 2020, the FDA denied Defendants' third citizen petition, filed December 23, 2019. The FDA noted that Defendants submitted a substantially similar citizen petition on July 1, 2019, and that the Agency denied the July 2019 Petition on November 27, 2019. The FDA acknowledged the additional statements directed to Sage's comments to the July Petition, but found that Defendants' responses "to the prior comment reiterate the assertions outlined above, which mirror the assertions in the July 2019 Petition." Given that Defendants' third petition was a retread of its second petition, no reasonable petitioner, including US WorldMeds, could have expected to succeed on the merits of its arguments. Nevertheless, US WorldMeds' third petition signaled to FDA that it could expect a further legal challenge upon approval of an ANDA.

123. Despite the FDA's eventual denial of all three petitions, collectively this series of petitions had Defendants' intended effect of complicating and delaying the review of Sage's ANDA. Defendants caused the FDA to undertake additional internal work and deliberations to provide justifications for its approval in the event that it faced a post-approval legal challenge. All of this delayed the FDA's final approval of Sage's ANDA.

E. US WorldMeds Sells Apokyn® Rights to Supernus

124. The September 2019 exclusionary agreement restricting access to compatible pens provides that "any Party hereto may assign its rights or delegate its obligations, in whole or in part, without such consent, to an entity that acquires all or substantially all of the business or assets of such Party to which this letter agreement pertains, whether by merger, reorganization, acquisition, sale, or otherwise."

125. In parallel with the FDA review of Sage's ANDA and Defendants' conspiratorial and exclusionary conduct, Defendant US WorldMeds was in the process of selling its business relating to Apokyn® and other assets. Defendant US WorldMeds undoubtedly sought to complete this sale before the FDA approved Sage's generic alternative to Apokyn® in order to keep its sale price up. US WorldMeds got the deal done.

126. On April 28, 2020, Defendant Supernus announced that it entered into a definitive agreement to "acquire the CNS portfolio of US WorldMeds." On June 9, 2020 (the Closing Date), Supernus completed its acquisition of all of the outstanding equity of US WorldMeds Enterprises, LLC (USWM Enterprises) pursuant to a Sale and Purchase Agreement with Defendant US WorldMeds Partners, LLC (i.e., Defendant "US WorldMeds"), dated April 28, 2020.

127. On a May 2020 call following the announcement of an agreement to acquire the business, Supernus explained that the transaction brought Supernus three established and marketed products and a product candidate in late-stage development. In 2019, these products generated net sales of approximately $150 million, with APOKYN® representing approximately $118 million of that amount. The deal structure consisted of an upfront payment of $300 million and up to $230 million in regulatory and commercial milestones.

F. Sage and TruPharma Prepare to Launch Upon the FDA's August 25, 2020 Target Approval Date

128. As indicated above, FDARA created a new type of 180-day marketing exclusivity period for ANDA applicants of certain drugs that the FDA has designated as CGTs. Specifically, section 808 of FDARA amended the FD&C Act by adding provisions at section 505(j)(5)(B)(v) and 505(j)(5)(D)(iv) of the FD&C Act to recognize a 180-day period of exclusivity (hereafter, CGT exclusivity) vis-à-vis certain other ANDA applicants to the first approved applicant that: (a) obtains approval of an ANDA for a drug that has been designated as a CGT and for which there were no unexpired patents or exclusivities listed in the Orange Book for the relevant RLD at the time the applicant submitted the original ANDA to the Agency; and (b) commercially markets such drug within 75 calendar days after the approval of the ANDA.

129. Importantly, the 180-day CGT exclusivity period described under section 505(j)(5)(B)(v) of the FD&C Act is triggered by the "first commercial marketing of the competitive generic therapy by any first approved applicant." The FDA has interpreted this section as providing that it is not restricted from approving other ANDAs covering a drug that is the same as the CGT prior to or after the approval of a first approved applicant's ANDA for the CGT *unless and until* the first approved applicant has commenced commercial marketing and triggered the exclusivity period. Therefore, the FDA's published guidance directs that in order to take full advantage of CGT exclusivity, first approved applicants should be prepared to begin commercially marketing the drug products approved under their ANDAs as soon as possible. The guidance continues: "For planning purposes, applicants can use their assigned GDUFA goal date as a guide to when action is expected."

130. It had always been Sage's plan to launch its product promptly upon approval. Sage partnered with TruPharma to handle the sales, marketing, and distribution of its generic

apomorphine cartridge product. TruPharma is an established sales and marketing company, with seasoned commercial personnel who have executed hundreds of product launches, including many first-to-market launches.

131. As of May 2020, Sage's ANDA had a goal date of August 25, 2020. Based on the minor nature of the remaining issues, it appeared that this would be the final complete response letter, and that final approval should be received on or before the August 25, 2020 goal date. Consistent with FDA guidance, Sage was by this time building inventory to be ready to launch upon approval.

132. Sage spent millions of dollars in out-of-pocket costs to complete validation and build inventory necessary to launch the product and perfect its CGT exclusivity. The product had 24 months of shelf life from the start of manufacture. Given the time required to manufacture and test product, and then to complete secondary packaging, finished product generally arrives at a commercial warehouse with at most 21 months remaining shelf life. Generally, customers will only accept generic product that has at least 10-12 months of shelf life remaining. Therefore, every month delaying FDA approval not only delays the launch of a generic competitor, but it also renders existing inventory shorter dated and less saleable.

133. In anticipation of FDA approval, TruPharma began to contact customers and to discuss contracts for the sale of Sage's generic product upon FDA approval. Apomorphine injection requires a physician's prescription, and prescriptions for Apokyn® generally can only be filled by one of three specialty pharmacies: Accredo Health Group, Inc. ("Accredo"), CVS Specialty Pharmacy ("CVS Specialty") and Optum Rx Specialty ("Optum").

134. In most instances and given that many states have mandatory substitution laws, the first generic typically can expect to capture as much as 80% of the market by pricing its product

at a discount to the brand list price. Based on this experience and estimated demand figures that buyers provided to TruPharma, Plaintiffs reasonably expected that as a first generic to market with competitive pricing and 180-days of CGT exclusivity, Plaintiffs' generic product would capture a majority share by volume of the injectable apomorphine market within one year of launch. Generic substitution rates and overall generic volumes typically grow year over year, especially as more patients access the less expensive therapy.

G. Defendants Succeed in Delaying the Already Pushed Back FDA Approval Goal Date of August 25, 2020 to February 23, 2022

135. Typically, when a pending ANDA has a "goal date," the FDA issues a written letter on that date which is either a Final Approval or a complete response letter explaining any deficiencies and requesting that the applicant respond. With regard to Sage's pending ANDA, the FDA did not issue a letter. Rather, Sage received an email from the FDA project manager that stated:

> This correspondence is in reference to the GDUFA Goal Date of August 25, 2020 for ANDA 212025, Apomorphine Hydrochloride Injection, 30 mg/3 mL (10 mg/mL), single-patient-use glass cartridge for use with a reusable pen injector (APOKYN® Pen). It appears that we will not make the GDUFA Goal Date identified above for this application. We regret that we are unable to provide an action on the application by this date. However, we will continue to move this application forward in the regulatory review process as quickly as possible. You may contact me 3 weeks for an updated status regarding this application.

136. Thereafter, Sage continued to follow up with the FDA, including in a phone call on October 6, 2020. When Sage asked the project manager what was holding up the approval, she stated that no information was required of Sage. Rather, the Agency was deliberating complex issues and until those are resolved there's no action either way.

137. On October 21, 2020, after Sage left a message for the FDA Project Manager, she emailed Sage stating: "The application remains under review. At this time the agency has yet to

determine when an action will be taken. We continue to work on your ANDA and discussions are ongoing."

138. It was clear that Defendants' strategy of abusing the citizen petition process and restricting access to compatible pens in order to delay generic competition was working. Even though all three of its petitions were denied, the existence of these petitions and the restricted access to compatible pens complicated the FDA review process, and further delayed final approval of Sage's ANDA. Sage and its agents communicated with multiple points of contact at the FDA. The FDA informed Sage verbally that it had made an internal decision to approve Sage's ANDA. The FDA said that all of the regulatory issues had been resolved and the ANDA was otherwise in good shape. The FDA just needed more time to document the reasoning for its approval given the complexity of the policy issues raised during the process.

139. Defendants' repetitive submissions did not change the outcome of FDA approval process. The FDA ultimately approved Sage's ANDA on February 23, 2022, without adopting any of Defendant's additional requirements. Defendants' baseless petitions nevertheless delayed the final approval by causing the FDA to spend additional time addressing complex information and preparing internal "defensive" documentation to justify its approval in the event it had to publicly defend its decisions in yet another legal challenge brought by Defendants following final approval of the Sage ANDA.

140. These petitions were objectively baseless, and subjectively motivated to complicate and delay the FDA approval process of a competitor seeking to enter the marketplace. Viewed together, Defendants' serial petitions were deployed as a part of their overall strategy to delay would-be competitors from securing a required government approval. These petitions formed a pattern of baseless, repetitive claims that constitute an abuse of the citizen petition process.

Defendants abused the governmental process by lodging a series of sham objections in bad faith in order to delay FDA approval.

141. By delaying approval, Defendants reaped supracompetitive monopoly profits, injured plaintiffs, and caused patients and the payors to incur the bill. **According to the Center for Medicare/Medicaid Services, for 2020 alone, the United States government spent $107 million on Apokyn, at an average beneficiary cost of approximately $98,000 per patient**.

142. But for Defendants' restrictions around access to Apokyn® samples, US WorldMeds' citizen petition activity, and the exclusionary agreement restricting access to compatible pens, Sage would have secured final FDA approval of its ANDA years earlier. It also would have had access to compatible pens both during the FDA review process and at the time of launch. Had Plaintiffs had access to the same compatible, reusable pens from BD during FDA review, the generic could have been approved for use with a pen provided by Plaintiffs, rather than one controlled by Defendants. Having access to generic pens at launch further would have enabled incumbent pharmacies to resist Defendants' exclusionary and coercive threats and to quickly fill any prescription (new start or refill) with a generic cartridge. Defendants' illegal and exclusionary tactics amounted to a multi-part scheme to block, delay, and restrain lower-priced generic competition.

H. After Years of Delay, the FDA Approves Sage's ANDA on February 23, 2022 for Specific Use with Defendants' Apokyn® Pen

143. On February 23, 2022, Plaintiff Sage Chemical finally obtained FDA approval for its apomorphine ANDA. The FDA announced the approval on its website on February 24, 2022, in an announcement entitled "Approved First Generic for Apokyn Injection Cartridges Requires Separately Packaged Pen." *See* Ex. C.

144. As set forth in the announcement:

> The U.S. Food and Drug Administration has approved the first generic of Apokyn (apomorphine hydrochloride injection) drug cartridges to treat hypomobility "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) associated with advanced Parkinson's disease.
>
> Prescribers and pharmacists should be aware that patients starting treatment with generic apomorphine hydrochloride injection will need to separately obtain the Apokyn Pen. This approval is for Sage Chemical Inc.'s application of the drug cartridges only, which are compatible for use with the Apokyn Pen, the brand-name pen injector. The Apokyn Pen is supplied by the brand manufacturer, is distributed and packaged separately, and is generally only dispensed through specialty pharmacies.
>
> Patients should first obtain the prescribed Apokyn Pen through a specialty pharmacy before being prescribed the generic apomorphine hydrochloride injection. Patients on established generic apomorphine hydrochloride injection who need a replacement Apokyn Pen may also only obtain an Apokyn Pen separately from the brand manufacturer.
>
> Additionally, prescribers, pharmacists, and patient advocates should ensure that patients with Parkinson's disease who are prescribed the brand-name Apokyn cartridges or the generic apomorphine hydrochloride cartridges understand generic substitution in their state and how it affects the patient's apomorphine hydrochloride injection prescription.
>
> Ex. C.

I. Specialty Pharmacies Entered into Contracts to Buy Plaintiffs' Generic Apomorphine Injection Drug Cartridges Upon FDA Approval

145. Plaintiffs had been preparing for the February 2022 FDA approval for years. TruPharma had already been in contact with buyers for the three major network pharmacies selling Apokyn®. Accredo contracts for generic products through its participation in the Econdisc Group Purchasing Organization and has authorized Econdisc to contract on its behalf. CVS and Optum similarly contract for generic products through their agent, Red Oak Sourcing, LLC. TruPharma [redacted] knew that Defendants maintained control over the supply of Apokyn® pens (made possible by its exclusionary agreement restricting access to compatible pens). [redacted]

146. [redacted]

147. The vast majority of prescriptions, including those for Apokyn® cartridges, are dispensed as refills. [redacted]

148. [redacted]

149. [redacted]

150. Upon approval, TruPharma quickly completed contracts with the three incumbent specialty pharmacies to supply them with generic cartridges for their patients. [redacted]

151. In March 2022, consistent with these contracts, [redacted] TruPharma accepted these orders and shipped the generic cartridge product.

J. Supernus Unlawfully Maintained its Monopoly by Coercing Pharmacies to Exclude Generic Competition and by Tying Higher-Priced, Branded Apomorphine Cartridges to Branded Injection Pens

152. While Defendants had succeeded in delaying competition for years, they now faced the real and significant risk of loss of market share for Apokyn®. Defendants then took urgent, additional exclusionary steps to block generic competition in the marketplace in order to maintain the Apokyn® monopoly.

153. Having taken over the mantle from US WorldMeds, Defendant Supernus now aggressively interfered with Plaintiffs' contracts and exercised its monopoly power by coercing the pharmacies to cancel orders pursuant to signed contracts for the generic apomorphine cartridges in order to exclude generic competition and unlawfully maintain its monopoly.

154. Despite FDA approval of generic apomorphine cartridges for specific use with the Apokyn® pen, when Supernus learned of the FDA's approval of Sage's ANDA and all three members of its pharmacy network had contracted with TruPharma to purchase generic cartridges,

[redacted]

155. These and other threats worked. Supernus successfully coerced all three of the network pharmacies to renege on their contracts with TruPharma, to cancel orders, and to return generic product received at their pharmacies or by their designated wholesaler.

156. [redacted]

[redacted]

157. [redacted]

158. [redacted]

159. [redacted]

160. Supernus's interference with pharmacies' ability to dispense the generic apomorphine refill cartridges for use with the reusable pens directly subverts the very manner in which the FDA intended for the generic to be administered and subverts the legislative intent of the Hatch-Waxman Act and the CGT provisions of FDARA aimed at increasing competition with

off-patent branded drug products. Supernus's anticompetitive agreements with pharmacy customers seeking to impose anticompetitive post-sale restrictions on the use of Apokyn® pens also cannot be justified on the basis either that the brand is covered by a patent (it is not), nor on the basis that the pen and cartridges together are a purported "combination product." Such post-sale restrictions have been repeatedly rejected by the FDA in specific response to US WorldMeds' sham citizen petitions as well as by the Federal Circuit and the Supreme Court in similar situations.

161. To the contrary, Defendants' coercion forcing pharmacies to agree not sell generic apomorphine cartridges or else be cut off from the supply of Apokyn® pens and/or cartridges violates the law in multiple ways.

162. First, by coercing pharmacies to cancel purchase order contracts for generic apomorphine cartridges, Supernus tortiously interfered with Plaintiffs' contracts and prospective business advantage.

163. Second, Supernus's coercion of pharmacy customers to force them to boycott a new market entrant was predatory and exclusionary conduct that impairs the opportunities of rivals and does not further competition on the merits, but rather was executed with the blatant purpose and effect of maintaining Supernus's monopoly over injectable apomorphine in violation of Section 2 of the Sherman Act and state antitrust law. Threatening to cut off supplies of compatible injector pens is particularly coercive and exclusionary where, as here, the buyers cannot go without the seller's product.

164. Third, this conduct violates the plain text of Section 3 of the Clayton Act, which makes it unlawful to "make a sale or contract for the sale of goods" on the condition that the purchaser "shall not use or deal in the goods … of a competitor" where the effect "may be to substantially lessen competition or tend to create a monopoly in any line of commerce."

165. Fourth, Supernus's threats not to supply Apokyn® pens unless pharmacy customers purchase branded cartridges and/or not generic apomorphine cartridges constitute unlawful tying under Sections 1 and 2 of the Sherman Act, Section 3 of the Clayton Act, and other antitrust laws. Defendants have expressly conditioned the ability to purchase the tying product, i.e., the compatible pen, on the buyer's agreement to purchase a different, tied product, i.e., Apokyn® cartridges, and/or *not* to purchase generic apomorphine cartridges, even for refill purchases.

166. Defendants' imposition of these exclusionary tying agreements on pharmacy customers substantially foreclosed, and indeed have blocked, Plaintiffs' access to the most efficient and critical distribution channels for generic apomorphine cartridges. Indeed, Defendants' have blocked all or nearly all access to the distribution channels in which branded Apokyn® is sold, and thus would be substituted with the generic, and in which the compatible pens are distributed.

167. While the cancelling of orders demonstrates an actual anticompetitive effect on the market, per se condemnation of this conduct without inquiry into actual market conditions is also appropriate in this case because Supernus exploited control over the tying product (the Apokyn® pen) to force the buyer into the purchase of a tied product (Apokyn® cartridges) that the buyers might have preferred, and indeed tried to, purchase elsewhere on different terms.

168. Defendants' tying agreements affect a substantial amount of interstate commerce, with payers spending more than $100 million on Apokyn® per annum, and Defendants have actually tied the sale of two distinct products, namely the Apokyn® pen and the Apokyn® cartridges sold separately for use with those pens.

169. As the FDA observed in its announcement of the approval of generic apomorphine cartridges and Defendants pointed out in their own citizen petitions, the "APOKYN® Cartridges and the APOKYN® Pen are distributed and packaged separately." Ex. C.

170. Indeed, the pharmacies' orders of generic apomorphine cartridges and patients seeking to purchase the generic cartridges demonstrate that there is demand for the cartridges to be offered separately from the pen.

171. By virtue of their exclusionary agreement restricting access to compatible pens, Defendants further have appreciable market power, and indeed monopoly power, in the tying market for compatible pens suitable for dispensing apomorphine cartridges, as demonstrated by Supernus's ability to require purchasers to accept terms that could not be extracted in a competitive market; to exclude competitors; to leverage its unique pens to restrain sales of generic apomorphine cartridges, and to continue to raise Apokyn® prices even in the face of generic competition.

172. As Supernus has admitted there is no "alternative auto-injector or injector pen separately approved or cleared by the FDA with technical specifications and/or intended uses compatible with this use" such that the compatible pen is a unique product that provides Supernus an advantage not shared by competitors with respect to the tying product.

173. Having control over the FDA-approved, compatible injector pens has enabled Supernus to extract exclusionary terms from pharmacy customers that they would not have agreed to in a competitive market, as made clear from their initial orders before Supernus exercised its monopoly power to exclude generic competition. Defendants have thus succeeded in substantially foreclosing access to the distribution channels generic competitors need access to in order to

meaningfully compete with Supernus by wielding the economic power derived from the unlawful monopoly of the compatible apomorphine injector pen market.

174. Finally, Defendants' agreements with pharmacies, as well as their agreement restricting access to compatible pens, constitute unlawful exclusive dealing agreements that violate Sections 1 and 2 of the Sherman Act, Section 3 of the Clayton Act, and state antitrust law. These exclusionary exclusive dealing agreements with pharmacies encompass both those that restricted RLD sales and samples when Sage was seeking FDA approval and those entered, amended, or enforced after FDA approval restricting access to compatible injector pens and preventing sales of generic apomorphine cartridges. These agreements are unreasonably restrictive, entered or enforced with the exclusionary purpose and effect of blocking generic competition and maintaining Defendants' monopoly profits and prices, and have substantially foreclosed competitors' access to products and the most efficient and critical distribution channels needed to meaningfully compete and challenge Supernus's monopoly.

175. The exclusionary provisions in these agreements cannot be justified by any procompetitive purpose. For example, Supernus is not protecting against free-riding on *its* investments, but is rather blocking competitors from accessing compatible pens and distribution networks that *others* created in order to substantially foreclose access to resources and distribution channels needed to compete with Supernus. Defendants have no patent rights capable of justifying unlawful post-sale restrictions on compatible pens that were created by BD and were not responsible for creating the pharmacy distribution networks that they now block. Indeed, even if Defendants *did* have patent rights that have been undisclosed to date, they would be exhausted under the first-sale doctrine long-established under Supreme Court precedent and could not

prevent patients from lawfully using Apokyn® pens to administer injections using generic apomorphine cartridges sold by Plaintiffs.

176. Even if some restrictive provisions in Defendants' contracts were reasonably necessary to protect legitimate investments into the creation of compatible pens or pharmacy distribution networks, which they are not, these provisions still violate the antitrust laws because they impair the opportunities of rivals in an unnecessarily restrictive way.

177. Nor are Defendants' anticompetitive restrictions justifiable based on safety or efficacy considerations. To the contrary, the FDA expressly approved Plaintiffs' generic apomorphine cartridges *for specific use with* Apokyn® injector pens. To the extent Defendants' had any legitimate safety or efficacy concerns regarding the use of some other, unapproved, and as of yet non-existent apomorphine cartridges, these concerns could be alleviated by the less restrictive alternative of Defendants updating their false advertising materials claiming that Apokyn® is the only FDA-approved therapy of this kind so prescribers and patients are made aware that there are now just two such apomorphine cartridge products approved for the safe and effective use with the Apokyn® pen.

178. These exclusionary tying agreements with pharmacies and the exclusionary agreement with BD have been effective. All three of the pharmacies or their agents currently servicing prescriptions for Apokyn® capitulated to Defendants' terms and cancelled contracts with TruPharma, thereby foreclosing nearly all access to injectable apomorphine cartridge refills. The pharmacies' capitulation to Supernus's coercion is particularly extraordinary given mandatory generic substitution laws and the substantial price gap between the branded and generic apomorphine cartridges.

179. Supernus's own statements to the SEC confirm that its agreements with specialty pharmacies have substantially foreclosed critical distribution channels and the market available for the generic substitution of Apokyn®. As Supernus admits, "The majority of sales of APOKYN are made to specialty pharmacies, including Accredo Health Group, Inc. and Caremark LLC." As Supernus noted in 2021, for the prior year, just "two specialty pharmacies, Accredo Health Group, Inc. and Caremark LLC accounted for more than 35% individually and more than 80% collectively of the total revenue from sales of APOKYN."

180. These exclusionary agreements have also caused an actual adverse effect on competition, including by: forcing pharmacies to cancel orders for generic apomorphine cartridges; blocking and restraining generic entry; limiting the output of generic apomorphine cartridges; restraining the accessibility of this important therapy for those suffering from advanced Parkinson's disease; limiting patient, prescriber, and payer choice; and by enabling Supernus to continue to raise prices for Apokyn® and to charge pharmacies about twice as much as they would otherwise pay for generic apomorphine cartridges.

181. The exclusionary purpose and effect of the agreement with BD and the tying agreements with customers has been further confirmed by Defendants' recent admissions. For example, during a February 28, 2022 call just days after the FDA granted Sage's ANDA final approval, Supernus's CEO made clear Defendants' plan to block typical generic substitution by tying cartridges to the injector pens:

> Jack A. Khattar -- President, Chief Executive Officer and Director
> Recently the company became aware of an approval of a generic to the Apokyn® injection cartridge. **The timing of availability of such a product is still largely unknown and the generic cartridge will still need to be paired with the Apokyn® Pen to administer the apomorphine injection.**
>
> ***
>
> **As I noted in my remarks, the cartridge will require the use of our pen. So it's not going to be a similar situation as if this were an oral tablet or capsule that**

> **is quickly substitutable. So the impact for this year may be limited.** Again, it all depends on the timing of -- and the availability of that product to start with. And then secondly, depending on all the logistics and the tactics surrounding an availability of a generic product. (Emphasis added.)

182. Two months later, during a May 9, 2022 earnings call, Supernus's CEO told investors in response to a question "why can't [the] generic just be used for the refills" that:

> **[C]learly, the cartridge that was recently approved as a generic to our cartridge still have to be used with our device and our pen. So that will not be available for the generics, obviously.** So we view that situation so far has been evolving in the right direction for us. As I mentioned in my prepared remarks, we haven't seen any significant impact of the business as of today. (Emphasis added.)

III. Supernus Willfully and Falsely Advertises That Apokyn® Is the "Only FDA-Approved Therapy" for Off Episodes

183. Defendants were carefully monitoring FDA approval of generic apomorphine cartridges. In its April 13, 2022 10-K, Supernus acknowledged that:

> In February 2022, the FDA approved the first generic of Apokyn® (apomorphine hydrochloride injection) to treat hypomobility "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) associated with advanced Parkinson's disease. This approval is for an application of the drug cartridges only, which are compatible for use with the APOKYN® pen, the brand-name pen injector.

184. Notwithstanding knowledge that the FDA approved a generic apomorphine cartridge in February 2022, to this day, Supernus's website advertising to prescribers continues willfully to state that "**APOKYN is the only FDA-approved therapy in the United States for the acute intermittent treatment of hypomobility—*off* episodes**." *See* Ex. D (emphasis added).

185. This claim is literally false and misleading, as Supernus knows.

186. It is also willfully false, as demonstrated by Supernus's SEC disclosures.

187. Moreover, the statement that Apokyn® is the only FDA-approved therapy of this kind appears as the very first sentence in the "About APOKYN" section of the website, not in a footnote or someplace hidden deeply within the website that could have been inadvertently missed.

188. This website page is directed to prescribers and is a key tool in advertising Apokyn®.

189. As prescribers may not substitute Apokyn®, a prescription-only medication, with therapies that are not approved by the FDA, Supernus's literally false statement that it is the only FDA-approved therapy for this use is also clearly material and likely to induce reasonable reliance. Given the sheer number of medications approved by the FDA, many prescribers assessing whether to prescribe Apokyn® would not otherwise have knowledge that a generic cartridge has been approved by the FDA. Prescribers would reasonably expect the brand company to be closely monitoring FDA approval of any generic alternatives and would not expect a public company like Supernus that touts itself as an "award-winning biopharmaceutical company with more than 30 years of experience" to make such a literally false statement on its website. Supernus's false statements have also persisted for a prolonged period of time since at least February 2022 and are not readily susceptible to neutralization as Plaintiffs have no way of knowing what prescribers or patients have visited Supernus's website and have thus been exposed to its false advertising.

190. By falsely claiming that Apokyn® is the only FDA-approved therapy to treat acute intermittent treatment of hypomobility—*off* episodes in the United States, Supernus artificially depresses demand for generic apomorphine cartridges. Prescribers checking this web page would see this statement, be misinformed as a result, and then prescribe the branded drug without demanding that specialty pharmacies make the generic available to patients at more affordable costs.

191. Supernus's false statements about important characteristics of its product and of the generic are thus another means of unfair competition and deceptive conduct being used to stifle Plaintiffs' market entry.

IV. Defendants Have Harmed Competition, Patients Suffering from Advanced Parkinson's Disease, Payers, Pharmacies, and Plaintiffs

192. Defendants' anticompetitive acts have harmed the competitive process and competition on the merits. As demonstrated by the orders customers were forced to cancel, in a competitive market, prescribers, pharmacies, and patients would have chosen lower-priced generic apomorphine cartridges over Apokyn® cartridges based on the merits if competition were not restrained by Defendants' exclusionary conduct. The competitive process for purchases of compatible apomorphine injector pens has likewise been harmed. Indeed, Defendants' agreement restricting access to compatible pens is so unreasonably restrictive that competitors cannot even negotiate to offer more competitive terms to purchase compatible, reusable pens capable of FDA-approval with the generic cartridges.

193. By harming competition, Defendants' unlawful conduct has caused actual adverse effects, which include Defendants' continued price increases on top of already monopolistic pricing; the elimination of customer, prescriber, and patient choice that would otherwise exist; reduced output of both generic apomorphine cartridges and compatible injector pens; restrained resale competition; and most importantly, the unnecessary suffering of patients living with advanced Parkinson's disease who would otherwise have greater and more affordable access to apomorphine injections needed to treat unexpected and crippling hypomobility experienced during "off" episodes.

194. Plaintiffs, patients, pharmacies, and payers have suffered substantial economic injuries that flow directly from the reduction in competition caused by Defendants' exclusion of generic competition. These injuries continue to grow as a result of Defendants' anticompetitive conduct that continues to this day. These injuries are quintessential antitrust injuries in that they flow directly from facially anticompetitive supracompetitive pricing and restrained output caused

by excluding and foreclosing generic competition from the market—exactly the harm the antitrust laws aim to prevent.

A. Defendants' Exclusionary Conduct Has Restrained Price Competition Enabling Supernus to Continue to Charge Supracompetitive Prices and to Harm Patients, Payers, and Pharmacies

195. Defendants' unlawful scheme has cost, and continues to cost, U.S. payers of apomorphine self-injection cartridges (including state and federal governments) tens of millions of dollars a year in excess payments.

196. Defendants' anticompetitive conduct delayed FDA approval and the entry of a generic apomorphine cartridge. Absent Defendants' conduct, Sage's generic version of Apokyn® would have entered the market no later than the second half of 2019.

197. Defendants' agreements prohibiting the resale of Apokyn® impeded the review and approval of Sage's ANDA, and therefore potential generic competition, by delaying Sage's ability to procure Apokyn® samples to satisfy FDA's comparative testing requirements. Absent these restrictions, Sage could have purchased sufficient quantities of Apokyn® through ordinary distribution channels.

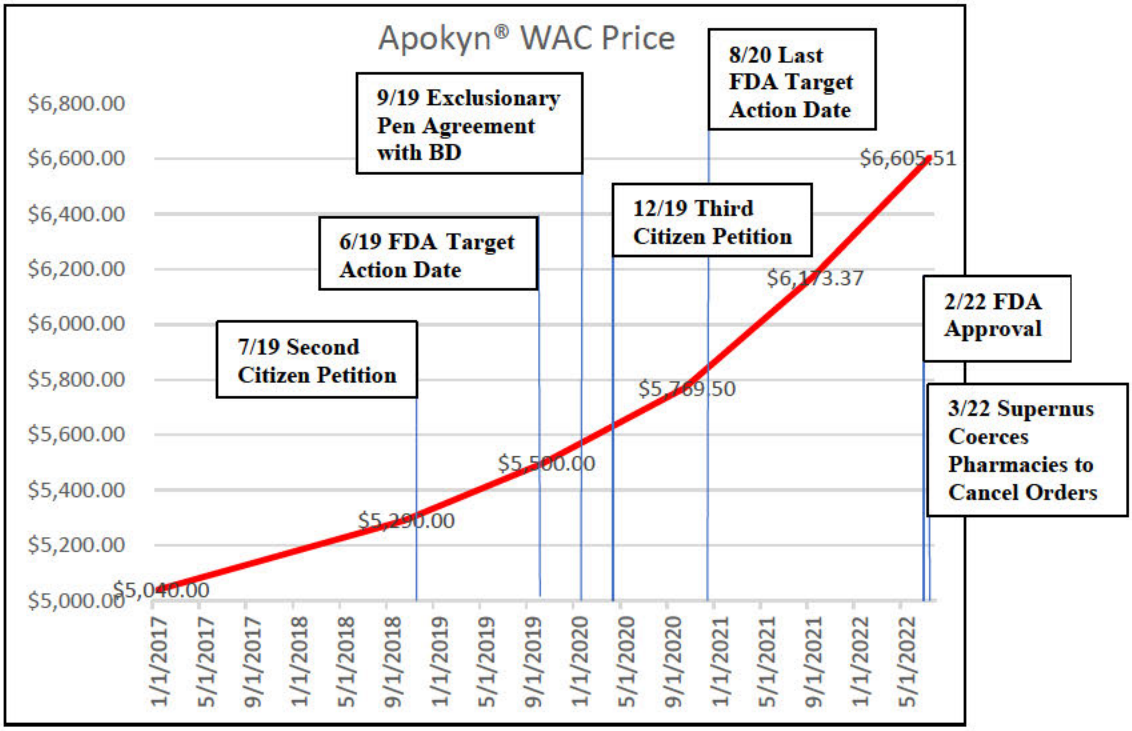
198. Defendants' series of sham petitions complicated the FDA review process and led to additional delays.

199. Defendants' exclusionary agreement with BD—the only supplier of compatible pens approved by the FDA—similarly impeded the FDA review process and delayed FDA approval by preventing Sage from obtaining compatible pens to respond to the arguments raised in Defendants' sham citizen petitions. Absent this agreement, Sage could have sourced these compatible pens from BD and rendered the citizen petition arguments moot.

200. By delaying generic competition, Defendants' anticompetitive conduct denied patients suffering from advanced Parkinson's disease and other purchasers of Apokyn® access to

an A-rated generic version of Apokyn® that would offer the same therapeutic benefit at a price roughly half of the monopolistic prices charged by Supernus. Absent Defendants' restrictions, most patients would have purchased the lower-priced, A-rated substitute for Apokyn® rather than the higher-priced branded product. Defendants' anticompetitive conduct, however, forced patients and payers to continue paying Defendants' ever-increasing monopoly prices for Apokyn® by depriving them access to a lower-cost, generic alternative.

201. As shown in the chart below displaying Defendants' wholesale acquisition cost ("WAC") pricing to pharmacies, Defendants' anticompetitive conduct has enabled Supernus, and US WorldMeds before it, to exercise its monopoly power by continuously raising Apokyn® prices above already supracompetitive levels. Supernus has continued to exploit patients suffering from advanced Parkinson's disease and payers for Apokyn® by continuing to this day to increase prices as a result of its ability to block generic competition. ***In the last five years alone, Supernus, and US WorldMeds before it, has raised the price of Apokyn® by more than 30%.***



202. Defendants' anticompetitive conduct has caused, and is continuing to cause, substantial economic harm. In contrast to Supernus's exploitative monopoly prices, generic products must be sold to the large specialty pharmacies at negotiated direct or indirect contract prices, which are at a steep discount to the listed WAC price of Apokyn®. Patients and other payers of Apokyn® would have saved at least tens of millions of dollars a year by purchasing generic versions of Apokyn®.

203. Defendants' anticompetitive conduct, and the corresponding reduction in the availability of Apokyn®, has also resulted in harm to patients who could not afford the treatment, or delayed treatment until insurance covered it, leading to poor medical outcomes.

204. Patients that have been prescribed Apokyn® by their treating physicians rely on subcutaneous injections using the Apokyn® pen. Throughout the period when Defendants executed their successful scheme to delay FDA approval of a generic apomorphine product, this unlawful conduct deprived patients of a less expensive therapy and some patients had to forego the medication altogether.

205. Even today, very few patients (less than 1%) have been able to access generic apomorphine cartridges because of Defendants' anticompetitive conduct. Thus, as a result of Defendants' anticompetitive conduct, patients are still being deprived of access to a lower-cost generic form of apomorphine cartridges.

206. Besides Plaintiffs and patients suffering from advanced Parkinson's disease, the biggest financial victim of Defendants' scheme may be the federal government. The average age of onset for Parkinson's disease is approximately sixty (60). Therefore, most patients suffering advanced stages of Parkinson's disease are over the age of sixty-five and on Medicare. As indicated above, Medicare Part D has been the biggest payor of the approximately $100,000 per

year cost of providing Apokyn® to each Medicare beneficiary taking the drug to treat Parkinson's disease. The annual cost to Medicare for all beneficiaries is over $100 million.

207. Payers of pharmaceuticals, including state and federal governments, have overpaid for this medication on the order of tens of millions of dollars a year. This harm is on-going.

208. Absent Defendants' anticompetitive conduct, pharmacies, hospitals and long-term care facilities would have had access to lower-cost, generic versions of Apokyn® years earlier. Defendants' anticompetitive conduct has had the collateral effect of making it more difficult for some patients to obtain injectable apomorphine from hospitals or pharmacies. Absent relief, Defendants' anticompetitive conduct will continue and will cause additional harm to patients.

209. Pharmacies' ability to compete for resales has also been harmed by Defendants' exclusionary conduct by preventing pharmacies from competing on price and attracting customers based on sales of the substantially lower-priced generic.

210. Defendant Britannia has profited significantly as a result of Defendants' exploitative pricing and hefty royalty payments.

211. Defendant US WorldMeds profited not just from the exploitative pricing but also because the exclusionary conduct enabled US WorldMeds to obtain a supracompetitive profit from its sale of Apokyn® and related assets to Defendant Supernus.

212. Defendant Supernus has likewise benefited, and continues to benefit, from supracompetitive pricing and profits as a result of Defendants' anticompetitive scheme.

B. Defendants' Exclusionary Conduct Has Reduced the Output and Availability of Apomorphine Cartridges and Compatible Self-Injector Pens

213. Defendants have been able to maintain their supracompetitive prices for Apokyn® by artificially restricting the market for injectable apomorphine.

214. By delaying and excluding generic competition and cutting off access to compatible self-injector pens, Defendants have restrained the output of both apomorphine cartridges and compatible pens used for injections.

215. If patients were not constrained from purchasing generic cartridges at lower prices, overall sales of apomorphine cartridges would have grown as a result of greater access and affordability.

216. If Plaintiffs were not blocked from purchasing the compatible, reusable, self-injector pens from BD, Plaintiffs would also provide additional self-injector pens as well, increasing the overall output of pens.

217. Absent Defendants' exclusionary conduct, Plaintiffs would sell generic apomorphine cartridges and compatible, reusable, self-injector pens at substantially lower overall prices that would increase output and affordability. The ability to provide compatible pens alongside the generic apomorphine cartridges would enable Plaintiffs to expand the market by making initial sales to new patients who cannot otherwise afford Apokyn®, in addition to enabling patients seeking cartridge refills to purchase and use more refills than they otherwise would have at higher prices for Apokyn®.

C. Defendants' Exclusionary Conduct Causing Supracompetitive Pricing Follows a Prior Course of Unlawful Conduct Aimed at Increasing Prices

218. This is not the first time Defendants have engaged in improper conduct resulting in artificially inflated payments for Apokyn® under the Medicare program. On April 30, 2019, just months before executing the exclusionary agreement with BD, the United States Justice Department ("DOJ") announced that US WorldMeds LLC agreed to pay $17.5 million to resolve allegations that it violated the False Claims Act, 31 U.S.C. §§ 3729 et seq., by paying kickbacks

to patients and physicians to improperly induce prescriptions of its drugs, Apokyn® and Myobloc®.

219. As explained by the DOJ, when a Medicare beneficiary obtains a prescription drug covered by Medicare Part D, the beneficiary may be required to make a partial payment, which may take the form of a copayment, coinsurance, or a deductible (collectively "copays"). Congress included copay requirements in the Medicare program, in part, to encourage market forces to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can demand for their drugs. Under the Anti-Kickback Statute, a pharmaceutical company is prohibited from offering, directly or indirectly, any remuneration, which includes paying patients' copay obligations, to induce Medicare patients to purchase the company's drugs.

220. The DOJ claimed that US WorldMeds substantially increased the price of Apokyn® in or around January 2012, a decision that resulted in a corresponding increase to Medicare patients' copays—which for many patients exceeded $5,000 per year. The United States alleged that, from the time of the price increase through June 30, 2013, US WorldMeds illegally paid Medicare patients' Apokyn® copays through a third-party foundation. During the relevant time period, US WorldMeds allegedly knew it was the only donor to the foundation's Parkinson's Disease fund and that virtually all of the fund's donations were spent on Medicare Apokyn® patients. The United States alleged that these payments represented illegal inducements to patients in violation of the Anti-Kickback Statute and False Claims Act.

221. The United States also alleged that US WorldMeds paid kickbacks to two physicians to induce prescriptions of Apokyn® and Myobloc. Specifically, the United States alleged US WorldMeds paid these physicians excessive speaking and consulting fees and provided

impermissible entertainment, such as lavish meals, private plane rides, and all-expense paid trips with their spouses (including trips to the Kentucky Derby).

222. In the DOJ's April 2019 Press Release announcing the settlement, one of the lead prosecutors, U.S. Attorney John H. Durham for the District of Connecticut stated: "Pharmaceutical companies and other healthcare providers that pay kickbacks to patients and physicians to improperly induce drug prescriptions drive up the costs of health care and divert critical resources from the Medicare program."

223. Incredibly, a few months following this settlement, Defendants undertook a series of exclusionary actions, including the agreement restricting access to compatible pens to delay and restrain generic competition to Apokyn®, which had the direct effect of harming the same population of patients enrolled in Medicare Part D and causing the federal government and other payers to overpay for the product.

D. Defendants' Unlawful Conduct Has Harmed Plaintiffs

224. Defendants' unlawful conduct has directly and proximately caused Plaintiffs Sage and TruPharma together to suffer millions of dollars of damages as a result of delayed and restrained market entry and competition, substantially foreclosed access to critical distribution channels and customers, lost profits due to higher costs of doing business, the loss of substantial sales, and the decreased ability to compete for compatible self-injector pen supply arrangements.

225. Prior to partnering with TruPharma, as a direct and proximate cause of Defendants' unlawful conduct, Plaintiff Sage was further damaged as a result of increased costs due to RLD restrictions, increased costs due to restrictions placed on the availability of compatible self-injector pens, and increased attorneys' fees and costs associated with the defense of US WorldMeds' sham citizen petitions that could have otherwise been used to compete against Defendants.

V. Direct Evidence of Monopoly Power Confirms Defendants Have Harmed Competition in Two Relevant Product Markets

226. There are two relevant product markets in which to evaluate Defendants' anticompetitive conduct: (1) the market for prescription-only, FDA-approved cartridges containing apomorphine hydrochloride for subcutaneous self-injection indicated for the acute, intermittent treatment of hypomobility, *"off"* episodes ("end-of-dose wearing-off" and unpredictable "on-off" episodes) in patients with advanced Parkinson's disease (the "Injectable Apomorphine Market"); and (2) the market for FDA-approved, reusable self-injector pens that are compatible with, and used to administer, subcutaneous injections of apomorphine hydrochloride (the "Compatible Apomorphine Injector Pen Market").

227. The Injectable Apomorphine Market encompasses apomorphine hydrochloride products that can be prescribed for subcutaneous self-injection and substituted interchangeably pursuant to FDA approval and state generic substitution laws—i.e., Apokyn® and A-rated injectable apomorphine hydrochloride bioequivalent products. Currently, Apokyn® and Sage's generic version of Apokyn® are the only two products in this market. As a result of Defendants' exclusionary conduct, Supernus currently controls more than 95% of this market.

228. The Compatible Apomorphine Injector Pen Market encompasses reusable self-injection pens that are FDA-approved to administer apomorphine hydrochloride doses from compatible cartridges. As a result of Defendants' exclusionary conduct, there are currently no other FDA-approved self-injector pens besides the Apokyn® pen that are compatible with cartridges used to dispense apomorphine hydrochloride such that Defendants currently control 100% of this market.

229. As a result of state generic substitution laws, FDA approval, and the unique characteristics of injectable apomorphine hydrochloride and the compatible pen needed to

administer doses thereof, there are currently no other reasonably interchangeable substitutes for the products in these markets, which is confirmed by Supernus's and previously US WorldMeds' ability to exercise monopoly power in these markets.

230. Defendants have exercised monopoly power both by controlling prices and by excluding competition. Defendants succeeded in excluding Plaintiffs from the Compatible Apomorphine Injector Pen Market by virtue of their exclusionary agreement that precluded Sage from purchasing and submitting compatible apomorphine self-injector pens for FDA approval along with its generic drug. Defendants also have succeeded in excluding Plaintiffs from the Injectable Apomorphine Market, most recently by enforcing exclusionary tying restrictions they could not have obtained in a competitive market.

231. Supernus, and US WorldMeds before it, has also been able to control prices and profitably increase its price for apomorphine cartridges and compatible injector pens by more than a small but significant and non-transitory increase in price, or "SSNIP", without a significant number of prescribers or patients switching away.

232. While referred to as the "hypothetical monopolist test," here the test demonstrates both that the metes and bounds of the markets are properly defined and that Supernus not only has monopoly power enabling it to control prices, but that Supernus has repeatedly exercised that monopoly power, as has US WorldMeds before Supernus. As shown above in the Apokyn® WAC Price Chart, despite FDA approval of a couple different types of therapies to treat symptoms during "off" episodes associated with Parkinson's disease, Supernus has repeatedly and profitably increased its prices by more than a SSNIP without losing significant sales to less expensive therapies.

233. For example, consistent with Supernus's key strategy to "drive growth and profitability" for Apokyn®, Supernus announced earlier this year that Apokyn® sales grew 34% in 2021, despite raising its price by 7% in 2021 alone. Indeed, Apokyn® sales have grown despite that fact that Defendants' price increases over just the last five years have exceeded a staggering and exploitative 30% increase.

234. These successive and profitable price hikes confirm that other Parkinson's disease therapies do not constrain Supernus's monopoly pricing and that prescribers or patients do not switch away to less expensive therapies in any amount significant enough to restrain Supernus's monopoly power. That leaves only mandatory state substitution laws applicable to the generic version of Apokyn® to provide a mechanism to bring price relief to the market, but the generic first has to gain access to the pharmacy distribution channels from which Plaintiffs are currently excluded by Supernus in order for market forces and the laws to work as intended.

235. As demonstrated by Defendants' successive, substantial, and profitable price increases, Apokyn® does not exhibit significant positive cross-elasticity of demand with respect to price with any product other than A-rated versions of Apokyn®.

236. Apokyn® and A-rated versions thereof further are differentiated from, and not reasonably interchangeable with, any other product on the market as a result of Apokyn®'s unique characteristics, effectiveness, ability to deliver rapid relief, limited side effects, and distinct means of delivery through self-injection.

237. Injectable apomorphine is uniquely able to quickly and effectively treat acute, unexpected, and sporadic episodes of hypomobility associated with advanced Parkinson's disease "off" episodes. As demonstrated by the insignificant number of prescribers switching patients to other treatments despite Defendants' repeated price hikes, other products that use a different

molecule may not be as effective for the treatment of the acute and sudden onset of hypomobility during "off" episodes in various types of patients.

238. As Jack Khatter, CEO of Defendant Supernus explained when his company acquired Apokyn®, apomorphine is truly unique as a treatment:

> Khatter: "And then finally, **as far as Apomorphine, I mean, as I mentioned earlier, it is really a very effective molecule**. You might recall, when we announced the transaction, we went through some clinical data actually on the Apomorphine, the pen as well as the [unapproved] pump. **The efficacy is really -- nothing really comes close to it**, although a lot of those data points are gathered from different studies and so forth." (Emphasis added.)

239. Unlike other treatments that are taken daily or intended to extend "on" periods and make primary Parkinson's medications like levodopa work longer, injectable apomorphine is unique in its ability to rapidly treat acute and disabling hypomobility attacks in as little as ten minutes when they unexpectedly occur.

240. Because Apokyn® and Sage's generic are the only apomorphine treatments that can be self-injected subcutaneously, they are also uniquely appropriate for patients with sensitivity to distinct side effects from treatments delivered in other forms. For example, Inbrija®, in addition to not being interchangeable because it uses levodopa instead of apomorphine, is an inhalable treatment that can be associated with upper respiratory infections and coughing. As discussed above, moreover, levodopa may be less effective as Parkinson's disease becomes more advanced over time. As another example, Kynmobi® is a sublingual film that can cause oral swelling, mouth ulcers, and nausea, requiring patients to premedicate with antinausea medications three days prior. Published studies further indicate that compared to Apokyn®, Kynmobi® achieves much lower bioavailability despite patients taking a much higher dose of Kynmobi®.

241. Indeed, Supernus's CEO Jack Khatter distinguished Kynmobi® on the basis that "[i]t's a sublingual tablet" and stated that "we believe the two products have very different profiles

and will end up really appealing to very different patient profiles," stressing that "the efficacy is very obviously very different." In another call, Mr. Khatter further explained that "the delivery of APOKYN in an injection pen is very, very different than a sublingual tablet."

242. Thus, Supernus, as well as the doctors that continue to prescribe Apokyn® despite steadily increasing prices, recognize that injectable apomorphine has unique characteristics and uses that make it best suited for distinct patients and conditions.

243. Another practical indication that injectable apomorphine constitutes its own relevant market is the distinct prices Supernus charges for Apokyn® compared to those noted above. For example, while the WAC price charged for Apokyn® is $6,605, it is only $842 for Kynmobi®. Even approximating on a per-dose basis, Apokyn® is on average five to six times more expensive than Kynmobi® and Inbrija®.

244. The fact that none of these other products have equivalent dosage forms is yet another practical indication that these other medications are not reasonably interchangeable with injectable apomorphine. As recognized by the FDA, drugs that are different dosage forms are not "pharmaceutically equivalent," and therefore are not considered "therapeutically equivalent" according to the FDA Orange Book.

245. Defendants sell and have sold Apokyn® at prices far above its cost of production, making it highly profitable. Even accounting for other direct expenses, Defendants' profit margins on Apokyn®'s net sales are substantial.

246. Defendants' monopoly power with respect to Apokyn® is durable and has persisted for an extended period of time, including more than ten years without patent protection. Throughout this period, Defendants have not only maintained, but repeatedly raised, its high price and continued to reap significantly higher profits.

247. Defendants have also publicly recognized that there is no "alternative auto-injector or injector pen" and that the unique characteristics and distinct uses of the Apokyn® pen preclude it from being reasonably interchangeable with any other type of injector pen such that it constitutes its own economic market. As US WorldMeds represented to the FDA in a citizen's petition:

> There is no other device constituent part, branded or generic, approved for this use with an apomorphine hydrochloride drug constituent part. **Nor, as noted, is there any alternative auto-injector or injector pen separately approved or cleared by FDA with technical specifications and/or intended uses compatible with this use**. Accordingly, in the absence of a device constituent part proposed in an ANDA, a generic drug constituent part would need to rely upon use with the APOKYN® Pen. (Emphasis added.)

248. Although injectable apomorphine cartridges and their compatible self-injector pens are complementary products, the demand for these products to be provided separately demonstrates that apomorphine cartridges and pens constitute distinct economic markets. As discussed above, a distinct demand for apomorphine cartridges is demonstrated by pharmacies' and patients' attempts to purchase Plaintiffs' generic apomorphine cartridges for refills on a stand-alone basis without purchasing a new pen. This separate demand is further confirmed by the FDA's explicit approval of Sage's ANDA for refill cartridges after being made fully aware by US WorldMeds that Sage's refill cartridges would need to be administered using Apokyn® pens. Indeed, the vast majority of Defendants' own sales of apomorphine hydrochloride are made as refills without an accompanying self-injector pen, which both US WorldMeds and the FDA have acknowledged is "distributed and packaged separately." A distinct demand for compatible apomorphine self-injector pens is similarly demonstrated by Sage's attempt to purchase pens from BD in order to provide pens for initial prescriptions in addition to just for refills.

249. Supernus has leveraged its monopoly over the Compatible Apomorphine Injector Pen Market to maintain and reinforce its monopoly power in the Injectable Apomorphine Market.

A. Barriers to Entry and Expansion Are High

250. Barriers to entry into the relevant antitrust markets are high because entering these markets requires overcoming substantial capital, technical, regulatory, and legal barriers.

251. In the United States, prescription drugs cannot be marketed and sold without FDA approval. Patients in the United States cannot be treated with prescription medications that have not been approved by the FDA. The FDA approval process creates significant barriers to entry for both the Injectable Apomorphine Market and the Compatible Apomorphine Injector Pen Market. This is one of the reasons Congress created the Competitive Generic Therapy approval pathway to address situations where, as here, the FDA determined that the branded drug in question faces inadequate generic competition.

252. Obtaining FDA approval for new apomorphine subcutaneous treatments is difficult and expensive. Prior to Sage's ANDA approval, no other company had obtained approval for a competitive generic to Apokyn®, despite the fact that Apokyn® has had no patent or regulatory exclusivity since April of 2011. To date, no company other than Defendants has obtained FDA approval for an apomorphine self-injector pen.

253. Even with FDA approval to start marketing generic apomorphine cartridges, no firm can currently sell a generic alternative to Apokyn® without patients having access to the Apokyn® pen. Defendants' unlawful restrictions on compatible pens have substantially foreclosed access and erected yet another barrier to market entry and expansion.

254. Defendants' exclusionary agreements with pharmacies have likewise created barriers to entry and expansion that are unlikely to be overcome without court intervention.

B. The Geographic Market Is the United States

255. The relevant geographic market is no larger than the United States. Pharmaceutical products are sold and regulated on a nationwide basis. Because the U.S. market is limited to FDA-

approved products, it can only include products approved for sale within the United States. Due to FDA regulations and the importance of this treatment, a small, but significant, and non-transitory increase in the price of injectable apomorphine cartridges or their compatible self-injector pens would not cause treating physicians and patients to substitute in significant numbers to other treatments or self-injector pens that are not available in the United States.

C. Defendants' Conduct Harms Interstate Commerce

256. The injectable apomorphine cartridges and compatible apomorphine self-injector pens at issue in this case are sold and distributed in interstate commerce. Defendants' unlawful activities, as alleged above, have occurred in, and have had a substantial impact on, interstate commerce, including by overcharging the federal government millions of dollars.

CAUSES OF ACTION

COUNT 1: AGREEMENTS THAT UNREASONABLY RESTRAIN TRADE, Violations of Section 1 of the Sherman Act, 15 U.S.C. §1, Section 3 of the Clayton Act, 15 U.S.C. §14, New Jersey Antitrust Act, N.J.S.A. 56:9-3

257. Sage and TruPharma incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

258. Defendants joined in a conscious commitment to a common scheme designed to achieve an unlawful objective—the suppression of price competition through the delay and restraint of generic competition.

259. Each Defendant has committed overt acts, as described above, in furtherance of this unlawful, common scheme that together and individually have unreasonably, substantially, and unjustifiably restrained competition in the relevant markets and that have caused actual adverse market effects by delaying and restraining competition; depriving customers, patients, and payers the benefits of price competition and lower prices; and by restraining output for both injectable apomorphine and compatible apomorphine self-injector pens.

260. As part of this overarching unlawful scheme to suppress price competition, Defendants have repeatedly violated the law by entering into anticompetitive agreements that have unreasonably and unjustifiably restrained competition, including at least:

a. agreements with distributors and/or pharmacies to restrict access to the RLD and Apokyn® pen;

b. the multi-year, exclusionary agreement between Defendants and BD for the exclusive supply of compatible pens for use with apomorphine to treat Parkinson's disease; and

c. Defendants' agreements requiring that pharmacies, distributors, and/or other customers only dispense branded Apokyn® cartridges to be used with the Apokyn® pen, and not dispense generic cartridges, including for refill prescriptions.

261. There is and was no legitimate, non-pretextual, procompetitive justification for Defendants' actions comprising the anticompetitive scheme, or the individual agreements that have furthered that scheme, capable of outweighing their anticompetitive effects. Even if there were some conceivable justification, Defendants' restrictive provisions and agreements are not reasonably necessary to achieve any such justification, which could have been achieved through less restrictive alternatives.

262. Defendants' conduct takes place in and restrains interstate commerce.

263. Plaintiffs Sage and TruPharma were injured in their business or property as a result of Defendants' anticompetitive agreements unreasonably restraining competition and have suffered and will suffer injuries directly and proximately flowing from the Defendants' restraints on competition.

264. Because this conduct involves exclusionary agreements between two or more unaffiliated entities, this conduct violates Section 1 of the Sherman Act, 15 U.S.C. § 1, and similar state laws. These exclusionary agreements also violate Section 2 of the Sherman Act, 15 U.S.C. § 2, and similar state laws because these agreements constitute anticompetitive acts intended to maintain Supernus's monopolies in the Compatible Apomorphine Injector Pen Market and Injectable Apomorphine Market.

265. The anticompetitive conduct alleged herein also constitutes a violation of the New Jersey Antitrust Act, N.J.S.A. 56:9-3, which prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy in restraint of trade or commerce" in the State of New Jersey.

COUNT 2: TYING
Violation of Sections 1 & 2 of the Sherman Act, 15 U.S.C. §§1, 2,
Section 3 of the Clayton Act, 15 U.S.C. §14,
New Jersey Antitrust Act, N.J.S.A. 56:9-3, 9-4(a)

266. Sage and TruPharma incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

267. Supernus's agreements with pharmacies, distributors, and/or other customers that require them to purchase Apokyn® apomorphine cartridges from Supernus, or at least not to purchase generic apomorphine from Plaintiffs, if they wish to purchase Apokyn® pens constitute unlawful tying arrangements.

268. These tying arrangements unreasonably restrain and substantially foreclose competition for the sale of injectable apomorphine cartridges and/or have maintained and extended Supernus's monopoly in the Injectable Apomorphine Market.

269. Injectable apomorphine cartridges and apomorphine self-injector pens are separate and distinct products.

270. Supernus has sufficient economic power in the Compatible Apomorphine Injector Pen Market to coerce pharmacies, distributors, and/or other customers to also purchase injectable apomorphine from Supernus even when they would prefer not to do so.

271. Supernus's tying arrangements affect a significant volume of interstate commerce.

272. These tying arrangements allow Supernus to maintain supracompetitive prices for injectable apomorphine that are ultimately passed on to end patients and/or payers, who are also harmed by virtue of having fewer injectable apomorphine options available, including at lower prices.

273. Supernus's tying arrangements have caused Plaintiffs substantial damages as a direct and proximate cause of this unlawful conduct because Supernus has foreclosed Plaintiffs

from competing for potential pharmacies, distributors, and/or other customers and deprived Plaintiffs of critical sales channels to end customers and patients.

274. Supernus's tying agreements are per se unlawful under the Sherman Act and violate the plain text of Section 3 of the Clayton Act.

275. However, alternatively, to the extent Supernus is permitted to defend its tying agreements under a "quick look" and/or rule of reason standard, there is and was no legitimate, non-pretextual, procompetitive justification for Supernus's tying restrictions capable of outweighing their anticompetitive effects. Even if there were some conceivable justification, Supernus's restrictive provisions and agreements are not reasonably necessary to achieve any such justification, which could have been achieved through less restrictive alternatives.

COUNT 3: MONOPOLIZATION
AND ATTEMPTED MONOPOLIZATION IN THE ALTERNATIVE
Violation of Section 2 of the Sherman Act, 15 U.S.C. § 2
New Jersey Antirust Act, N.J.S.A. 56:9-4(a)

276. Sage and TruPharma incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

277. As detailed above, Supernus and its predecessor US WorldMeds before it, possesses monopoly power in the relevant markets, including the power to control prices and/or exclude competition.

278. Supernus, and US WorldMeds before it, willfully engaged in exclusionary or predatory conduct that tends to impair the opportunities of rivals and also either did not further competition on the merits or did so in an unnecessarily restrictive way.

279. As alleged above, the exclusionary conduct perpetrated by Supernus, and US WorldMeds before it, had the effect of maintaining and extending each Defendant's monopoly power in one or both relevant markets.

280. Supernus and/or US WorldMeds has unlawfully maintained a monopoly in multiple ways that individually and together violate Section 2 of the Sherman Act and similar state laws, including by:

a. entering into exclusionary agreements with suppliers, pharmacies, distributors, and/or other customers to restrain market entry, restrict access to RLD samples, unreasonably restrain competition, exclude competitors, suppress price competition, limit output, and/or raise competitors' costs;

b. conspiring with Defendant Britannia to exclude generic competition, including by entering into an exclusionary agreement to restrain access to compatible apomorphine self-injector pens;

c. coercing pharmacies, distributors, and/or other customers to boycott and concertedly refuse to deal with Plaintiffs;

d. coercing pharmacies, distributors, and/or other customers not to purchase, dispense, and/or market generic apomorphine cartridges with threats they would be cut off from apomorphine products and/or compatible apomorphine self-injector pens or by otherwise tying the purchase of apomorphine cartridges to the purchase or compatible apomorphine self-injector pens;

e. filing objectively and subjectively baseless sham citizen petitions in bad faith for the purpose of interfering with Plaintiffs' ability to compete;

f. interfering with Plaintiffs' contractual and business relationships by coercing pharmacies to cancel or not complete orders;

g. raising rivals' costs above those that would exist under competitive conditions;

h. making false and material misrepresentations and omissions to pharmacies, prescribers, and/or patients, including but not limited to, falsely advertising that Apokyn® "is the only FDA-approved therapy in the United States for the acute intermittent treatment of hypomobility—*off* episodes;" and

i. leveraging the Compatible Apomorphine Injector Pen Market monopoly to maintain and extend the Injectable Apomorphine Market monopoly.

281. While these anticompetitive acts themselves constitute individual antitrust violations on a stand-alone basis, together they support a broader monopolization claim.

282. As a direct, foreseeable, and proximate result of Defendants' anticompetitive and monopolistic conduct, Plaintiffs have been injured in its business, all with resultant damages in

amounts to be proven at trial, in at least the following ways: (1) Plaintiffs' costs of doing business have been increased as a direct result of restricting RLD samples and compatible apomorphine self-injector pens; (2) Plaintiffs have been substantially foreclosed from competing in both the Injectable Apomorphine Market and the Compatible Apomorphine Injector Pen Market; (3) Sage has had to pay attorneys' fees and costs to defend against sham citizen petitions; and (4) Plaintiffs have lost business as a result of Defendants' anticompetitive conduct and interference with its contracts and relationships with pharmacies and with BD.

283. As a direct, foreseeable, and proximate result of Defendants' anticompetitive and monopolistic conduct, competition, pharmacies, distributors, payers, and patients have been harmed by, among other things: (1) Defendants' ability to charge supracompetitive prices; (2) the reduced output and availability of both injectable apomorphine cartridges and compatible apomorphine self-injector pens; (3) decreased competition for the manufacturing and supply of compatible apomorphine self-injector pens; (4) decreased price competition among pharmacies and other resellers; and (5) a reduction in prescriber, pharmacy, and patient choice.

284. This conduct has substantially foreclosed competition in the Compatible Apomorphine Injector Pen Market, which Supernus has further leveraged to tie and maintain its monopoly over the Injectable Apomorphine Market.

285. There is and was no legitimate, non-pretextual procompetitive justification for Defendants' exclusionary conduct that outweighs its individual and collective anticompetitive effects, and even if there was some conceivable justification, the exclusionary conduct at issue impairs the opportunities of rivals in an unnecessarily restrictive way.

286. Defendants' conduct has had a substantial effect on interstate commerce.

287. Supernus, and US WorldMeds before it, has also violated Section 2 of the Sherman Act and similar state laws by attempting to monopolize one or more relevant markets as well, as the conduct at issue makes clear that each specifically intended to maintain monopoly power in one or more relevant market. Both Defendants' conduct reflects a conscious objective to control prices and/or exclude competition.

288. Supernus, and US WorldMeds before it, had a substantial likelihood and/or dangerous probability of acquiring or maintaining monopoly power in relevant market and succeeding, to any extent it has not already, in its attempt to monopolize the Injectable Apomorphine Market.

289. The anticompetitive conduct alleged herein also constitutes a violation of the New Jersey Antitrust Act, N.J.S.A. 56:9-4(a), which makes it "unlawful for any person to monopolize, or attempt to monopolize, or to combine or conspire with any person or persons, to monopolize trade or commerce in any relevant market within this State."

COUNT 4: FALSE, DECEPTIVE, AND MISLEADING PROMOTION/ADVERTISING
Violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)

290. Sage and TruPharma incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

291. Supernus has willfully misrepresented and/or omitted material facts, qualities, and characteristics relating to Apokyn®, including but not limited to, falsely advertising that Apokyn® "is the only FDA-approved therapy in the United States for the acute intermittent treatment of hypomobility—*off* episodes" in advertising and promotional activity that took place in interstate commerce and, on information and belief, have been widely disseminated to substantial numbers of prescribers and patients who are actual and potential customers of Plaintiffs.

292. Supernus has willfully continued making these claims in spite of its awareness of their falsity and/or potential to mislead.

293. On further information and belief, these misrepresentations, collectively and individually, have in fact confused, misled, and deceived prescribers and patients, have depressed demand for Plaintiffs' generic apomorphine cartridges, deprived Plaintiffs of substantial sales, threaten the loss of substantial future sales, and have also caused significant harm to Plaintiffs' goodwill and reputation, further hurting Plaintiffs' ability to compete for future sales.

COUNT 5: TORTIOUS INTERFERENCE WITH CONTRACT

294. Sage and TruPharma incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

295. Plaintiffs had in place contracts to sell and distribute generic apomorphine cartridges to Accredo, CVS Specialty and Optum, and their respective wholesalers.

296. On information and belief, Supernus knew Plaintiffs had entered contracts with the customers above and/or their agents to sell generic apomorphine cartridges.

297. On information and belief, Supernus knew that interfering in these contractual relationships would cause injury to Sage and/or TruPharma.

298. Supernus intentionally, improperly, and without justification or excuse interfered with those contracts by restricting Accredo, CVS and Optum from administering generic apomorphine cartridges for use with the Apokyn® pen, including as refill prescriptions.

299. As a result of Defendants' intentional interference, Accredo, CVS and Optum have reneged or backed out of their agreements to purchase substantial quantities of generic apomorphine cartridges. Absent Defendants' wrongful conduct, Plaintiffs would have sold substantial quantities of generic apomorphine cartridges to these and other customers. Plaintiffs therefore have been damaged by Defendants' wrongful conduct.

COUNT 6: TORTIOUS INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE

300. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

301. As discussed above, Plaintiffs had in place contracts to sell and distribute generic apomorphine cartridges to Accredo, CVS Specialty, and Optum, and their respective wholesalers. However, Plaintiffs further had a reasonable expectation of selling additional substantial volumes of generic apomorphine cartridges through these entities and their business partners with which Supernus has interfered.

302. In addition, at times relevant to this action, Plaintiff Sage had in place an economic relationship with BD relating to injector pens for use with apomorphine, with the probability of assuring Sage, its marketing partner, pharmacies, and patients a supply of reusable pens compatible with its generic apomorphine cartridge product, which would have provided Sage future economic benefit.

303. On information and belief, Defendants knew of the relationship between BD and Sage and between Plaintiffs and the pharmacies and/or their agents.

304. On information and belief, Defendants knew that interfering in these relationships would cause injury to Sage and/or TruPharma.

305. Defendants intentionally, improperly, and without justification or excuse took actions to disrupt the relationship: (1) by coercing BD to violate its policy of generally not entering into exclusive agreements, to cease all discussions with Plaintiff, and to refuse future negotiations with Plaintiff; and (2) by coercing pharmacies to cancel their orders and not to place orders on an on-going basis.

306. Defendants' actions have in fact disrupted Plaintiff's relationship with BD and the pharmacies.

307. Plaintiffs have suffered great economic harm as a proximate cause of Defendants' actions.

DEMAND FOR JURY TRIAL

308. Sage and TruPharma hereby demand a jury trial on all of their claims.

PRAYER FOR RELIEF

309. Sage and TruPharma respectfully pray for the following relief:

a. Pursuant to 28 U.S.C. § 2201, a declaration that the exclusivity provisions in Defendants' agreement with BD are unreasonable and unenforceable restraints of trade that violate Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, Section 3 of the Clayton Act, 15 U.S.C. § 14, and the New Jersey Antitrust Act, N.J.S.A. 56:9-3, 9-4(a);

b. Pursuant to 28 U.S.C. § 2201, a declaration that that the restrictive provisions in Defendants' agreements with pharmacies, distributors, and/or other customers that restrain them from purchasing and/or selling generic apomorphine cartridges are unreasonable and unenforceable restraints of trade that violate Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, Section 3 of the Clayton Act, 15 U.S.C. § 14, and the New Jersey Antitrust Act, N.J.S.A. 56:9-3, 9-4(a);

c. Pursuant to 28 U.S.C. § 2201, a declaration that Supernus has unlawfully tied the sale of injectable apomorphine to the sale of compatible apomorphine self-injector pens by virtue of its exclusionary agreements with pharmacies, distributors, and/or other customers, in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, Section 3 of the Clayton Act, 15 U.S.C. § 14, and the New Jersey Antitrust Act, N.J.S.A. 56:9-3, 9-4(a);

d. Pursuant to 28 U.S.C. § 2201, a declaration that Defendants' unreasonably restrictive provisions are null and void and cannot be enforced against suppliers, pharmacies, distributors, customers, or other parties to the contracts;

e. Pursuant to 28 U.S.C. § 2201, a declaration that Supernus, and US WorldMeds before it, has monopolized, or in the alternative, attempted to monopolize, the Injectable Apomorphine Market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, and the New Jersey Antitrust Act, N.J.S.A. 56:9-4(a);

f. Pursuant to 28 U.S.C. § 2201, a declaration that Supernus, and US WorldMeds before it, has monopolized, or in the alternative, attempted to monopolize, the Compatible Apomorphine Injector Pen Market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, and the New Jersey Antitrust Act, N.J.S.A. 56:9-4(a);

g. Pursuant to 28 U.S.C. § 2201, a declaration that Defendants conspired to suppress price competition in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and the New Jersey Antitrust Act, N.J.S.A. 56:9-3;

h. Pursuant to 28 U.S.C. § 2201, a declaration that Supernus has engaged in false and/or misleading advertising and promotional activity in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a);

i. Pursuant to 15 U.S.C. § 15, compensatory and trebled damages, and attorneys' fees and costs, resulting from Defendants' violations of the Sherman Act and New Jersey Antitrust Act, N.J.S.A. 56:9-3, 9-4(a);

j. Pursuant to 15 U.S.C. § 26, permanent injunctive relief preventing Defendants from continuing the unlawful acts in violation the Sherman Act, the Clayton Act, and the New Jersey Antitrust Act;

k. Pursuant to 15 U.S.C. § 26, permanent injunctive relief preventing and restraining Defendants from tying the sale of injectable apomorphine to compatible apomorphine self-injector pens;

l. Pursuant to 15 U.S.C. § 26, permanent injunctive relief preventing and restraining Defendants from foreclosing Plaintiffs' access to compatible apomorphine self-injector pens;

m. Pursuant to 15 U.S.C. § 26, permanent injunctive relief prohibiting Defendants from denying patients access to the cartridges they need to receive subcutaneous injections of generic apomorphine;

n. Pursuant to 15 U.S.C. §§ 1116-17, permanent injunctive relief preventing and restraining Supernus from continuing its unlawful acts in violation of the Lanham Act, 15 U.S.C. § 1125(a), recovery of Supernus's profits and Plaintiffs' trebled damages resulting from Supernus's violations of the Lanham Act, recovery of the costs of this action, and attorneys' fees;

o. Pursuant to 28 U.S.C. § 2201, a declaration that Defendants tortiously interfered with Plaintiffs' contracts with specialty pharmacies and wholesalers;

p. Pursuant to 28 U.S.C. § 2201, a declaration that Defendants tortiously interfered with Plaintiffs' prospective economic advantage to be derived from expected pharmacy and distributor relationships and an expected

supply arrangement with BD for reusable injector pens compatible with its generic apomorphine cartridge product;

q. Pursuant to 28 U.S.C. § 2202, such further relief as may be necessary or proper based upon this Court's declaratory judgments;

r. Pre-judgment and post-judgment interest at the maximum legal rate;

s. Compensatory damages, treble damages, attorneys' fees, and costs, including expenses for discovery and document productions pursuant to the New Jersey Antitrust Act, N.J.S.A. 56:9-12; and

t. Such other relief as this Court may deem just and proper.

Dated: October 3, 2022

Respectfully Submitted,

By: */s/ Daniel R. Miller*

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